EXHIBIT 1

In Re:

Digitek

Suzanna Wolfe

January 21, 2010

Confidential – Subject to Further Confidentiality Review

GOLKOW TECHNOLOGIES, INC.

Excellence In Court Reporting For Over 20 Years

877.370.3377

deps@golkow.com

Original File sw012110.txt

Min-U-Script®

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

----------X

IN RE: DIGITEK : MDL NO. 1968

PRODUCTS LIABILITY LITIGATION :

----------X

THIS DOCUMENT RELATES TO :

ALL CASES :

----------X

CONFIDENTIAL - SUBJECT TO FURTHER

CONFIDENTIALITY REVIEW

Videotaped Deposition of Suzanna Wolfe

Thursday, January 21, 2010

a witness herein, taken on behalf of the Plaintiffs in the above-entitled cause of action pursuant to notice and the West Virginia Rules of Civil Procedure by and before Debra A. Volk, Professional Court Reporter and Notary Public within and for the State of West Virginia at the law offices of Jackson Kelly, PLLC, 150 Clay Street, Suite 500, Morgantown, West Virginia 26501, commencing at 11:40 a.m.

IN THE CIRCUIT COURT

OF KANAWHA COUNTY, WEST VIRGINIA

----------X

IN RE: DIGITEK LITIGATION : CIVIL ACTION NO.

----------X 08-C-5555

THIS DOCUMENT APPLIES TO :

Diana L. Adkins v. Mylan Pharmaceuticals, Inc., et al. C.A. No. 09-C-40KAN

Thomas Beveridge v. Mylan Pharmaceuticals, Inc., et al. C.A. No. 08-C-273-OHI

Carl Brown v. Mylan Pharmaceuticals, Inc., et al. C.A. No. 09-C-123 NIC

Elizabeth Byus v. Mylan Pharmaceuticals, Inc., et al. C.A. No. 08-C-1954 KAN

James R. Christian v. Mylan Pharmaceuticals, Inc., et al. C.A. No. 09-C-292 MON

John Anthony Conte v. Mylan Pharmaceuticals, Inc., et al. C.A. No. 08-C-1995 KAN

Martha Florence Guy MOA v. Mylan Pharmaceuticals, Inc., et al. C.A. No.08-C-303 OHI

Claude E. Jarrell v. Actavis Group, et al. C.A. No. 09-C-512 KAN

Bobbi J. Myers v. Mylan Pharmaceuticals, Inc., et al. C.A. No. 08-C-999 KAN

Melvin L. Pennington, et ux, v. Mylan Pharmaceuticals, Inc., et al. C.A. No. 08-C-172 PNM

Lola Jean Smith, et ux, v. Mylan Pharmaceuticals, Inc., et al. C.A. No. 08-C-1069 KAN

Russell A. Wells v. Mylan Pharmaceuticals, Inc., et al. C.A. No. 09-C-003 NIC

APPEARANCES:

On behalf of the Plaintiffs:

PETER A. MILLER, ESQUIRE
The Miller Firm, LLC
The Sherman Building
108 Railroad Avenue
Orange, Virginia 22960
Telephone: (540) 672-4224
Fax: (540) 672-3055
E-mail: pmiller@doctoratlaw.com

On behalf of the Plaintiffs:

CARL N. FRANKOVITCH, ESQUIRE
Frankovitch, Anetakis,
Colantonio & Simon
21 Twelfth Street, Suite 504
Wheeling West Virginia 26003-2839
Telephone: (304) 233-1212
Fax: (304) 233-1251
E-mail: carln@facslaw.com

APPEARANCES (Cont.):

On behalf of the Plaintiffs:

MEGHAN JOHNSON CARTER, ESQUIRE
Motley Rice, LLC
28 Bridgeside Boulevard
Mt.Pleasant, South Carolina 29464
Telephone: (843) 216-9383
Fax: (843) 216-9430
E-mail: mjohnson@motleyrice.com

On behalf of the Defendant, Mylan and Suzanna Wolfe:

MADELEINE M. MCDONOUGH, ESQUIRE
ERICKA L. DOWNIE, ESQUIRE
Shook, Hardy & Bacon, LLP
2555 Grand Boulevard
Kansas City, Missouri 64108
Telephone: (816) 474-6550
Fax: (816) 421-5547
E-mail: mmcdonough@shb.com
edownie@shb.com

APPEARANCES (Cont.):

On behalf of the Defendant, Mylan:

ERIK C. NAFT, ESQUIRE
Mylan
1500 Corporate Drive
Canonsburg,Pennsylvania 15317
Telephone: (724) 514-1897
Fax: (724) 514-1871
E-mail: erik.naft@mylan.com

On behalf of the Defendant, Actavis Totowa, LLC:

EDWARD E. TABER, ESQUIRE
Tucker, Ellis & West, LLP
1150 Huntington Building
925 Euclid Avenue
Cleveland, Ohio 44115-1414
Telephone: (216) 696-2365
Fax: (216) 592-5009
E-mail: etaber@tuckerellis.com

APPEARANCES (Cont.):

On behalf of all Defendants:

JAMES S. ARNOLD, ESQUIRE
Allen, Guthrie & Thomas, PLLC
500 Lee Street, East, Suite 800
Charleston, West Virginia 25301
Telephone: (304) 345-7250
Fax: (304) 345-9941
E-mail: jsarnold@agmtlaw.com

ALSO PRESENT: Greg Diefenbaugh, Videographer

I N D E X

E X H I B I T S

E X H I B I T S (Cont.)

O B J E C T I O N S

O B J E C T I O N S (Cont.)

* * *

P R O C E E D I N G S

* * *

VIDEOGRAPHER: The time is 11:40 and we're now on the record. This is the videotaped deposition of Suzanna Wolfe taken by the Plaintiffs in the matter of In Re: Digitek Products Liability Litigation being case number MDL-1968 in the U.S. District Court for the Southern District of West Virginia, Charleston Division held at the offices of Jackson Kelly in Morgantown, West Virginia on the 21st day of January 2010.

My name is Greg Diefenbaugh and I am the Video Specialist. The Court Reporter is Debbie Volk; we are both associated with Golkow Litigation Technologies. Would counsel please introduce themselves and who they represent?

MS. CARTER: Meghan Carter for the Plaintiffs.

MR. FRANKOVITCH: Carl Frankovitch for the Plaintiffs.

MR. MILLER: Pete Miller with Plaintiffs.

MS. MCDONOUGH: Madeleine

McDonough representing Mylan and the witness, Suzy Wolfe.

MS. DOWNIE: Ericka Downie representing Mylan and the witness, Suzy Wolfe.

MR. NAFT: Erik Naft for Mylan.

MR. TABER: Ed Taber for the Actavis defendants.

MR. ARNOLD: Jim Arnold for -- West Virginia counsel for all defendants.

VIDEOGRAPHER: Would the Court Reporter please swear in the witness?

* * *

SUZANNA WOLFE

being first duly sworn, was examined and deposed as follows:

* * *

E X A M I N A T I O N

BY MR. MILLER:

Q. Ma'am, we met earlier, but if you would please state your full name for the record.

A. Sure, it's Suzanna Wolfe. Please feel free to call me Suzy.

Q. Thank you. Before we get started I'd like to go over a of couple rules. If I ask a

question, I'm going to assume that you understand the question I asked and if you don't understand the question, I'm going to ask that you ask me to rephrase the question so you do understand; is that fair?

A. Sure, yes.

Q. This lady is trying to repeat everything we say so that sometimes it takes me a while to get the question out and we don't want to talk over each other, on top of each other, so if you wait until I'm done that would be great; is that fair?

A. Yes.

Q. Perfect. Have you ever been deposed before?

A. Once many years ago for a personal issue.

Q. Okay.

It had nothing to do with --

A. No, no.

Q. Okay.

What is your title at Mylan?

A. Currently my title is Third-Party Liaison for North America, and that's in the Global Quality Group.

Q. Third-party liaison -- third-party liaison for safety or for any specific issue or is it just?
third-party liaison?
A. For Quality Assurance.
Q. For quality assurance. And I've kind of heard it phrased a few different ways, when you say quality assurance, am I correct in saying that that is taking the quality control systems as two parts, quality control and quality assurance?
A. Yes, you could say that. Quality assurance is more oversight, so all of quality -- it depends how different companies are set up and established. Typically quality control is within quality assurance. In Mylan, that's the way our systems are set up. So quality control reports in through quality assurance.
Q. Okay.
And when you say at Mylan, you're discussing a product that would be made at Mylan, there's a quality control and a quality assurance that oversees that; is that correct?
A. Correct.
Q. So there would be no counterpart to

you that's quality controlled to third parties?
A. Exactly, that's right.
Q. So when it comes to safety issues or quality issues with third parties, you're it; is that fair?
MS. MCDONOUGH: Sorry, what do you mean by you're it? Objection.
MR. MILLER: Yeah, I guess you're it. Tag, you're it. That there's no one -- that there is no liaison at Mylan to third parties regarding quality control systems, it's all quality assurance?
THE WITNESS: Well, no, that's not true.
MR. MILLER: Okay.
THE WITNESS: This is my current job and my current job, third-party liaison, really, I'm just writing technical agreements for the global -- right now I work for Mylan, Inc.
MR. MILLER: Okay.
THE WITNESS: So I'm writing technical agreements for all of the sites within North America and Mylan.
BY MR. MILLER:

Q. How long have you been in that position?
A. In that position, going on two years now.
Q. Okay.
So we're at the beginning of 2010, okay, so the beginning of 2008. What was your title prior to becoming Third-Party Liaison for Quality Assurance?
A. I was quality assurance manager for outsourced products reporting in to MPI, Mylan Pharmaceuticals.
Q. Give me an overview, if you would please, when you say Mylan Inc. and Mylan Pharmaceuticals; what's the difference between those two?
A. Well, Mylan has become a global company within the last year, year and a half; Mylan has become global. In other words, acquiring businesses and entities and facilities around the world, globally. So we have a Mylan Inc. unit, we have global quality, which represents all of Mylan Inc., so all the regions around the world. MPI, Mylan Pharmaceuticals is strictly Morgantown, West Virginia. It's that

site, that manufacturing and packaging site.
Q. Okay.
And I want to focus then from 2008 or actually from April specifically of 2008 going backwards in time; is it fair to say that Mylan was not global during that time?
A. Correct.
Q. Okay.
And so Mylan -- is it fair to say that from April going back in time you were employed by Mylan Pharmaceuticals -- well, you said MPI, Mylan Pharmaceuticals, --
A. Inc.
Q. Inc., now I'm confused because I thought Mylan Pharmaceuticals, Inc. was the global --
A. Mylan Inc.
Q. Got you. All right.
It takes me a while; I'll catch on. How long did you have the title of quality assurance manager for outsourced products?
A. For -- I started in 2005, so from January of 2005 until 2008, probably the end of 2008, November, December.
Q. Okay.

So you had that title up to -- up through to 2008?
A. Right.
Q. Okay.
And when were you first hired by MPI?
A. January of 2005.
Q. So you were hired --
A. Yes.
Q. -- at that title, okay. What are the functions or the duties in your own words of what a quality assurance manager for outsourced products does? What's a daily function?
A. Well, the job responsibilities were to review documentation and released product that was manufactured by outsourced companies, which means companies that manufacture or package for Mylan.
Q. And you understand that this case is about the product Digitek?
A. Yes.
Q. And it's fair to say that Digitek was one of the outsourced products during that time?
A. Yes, it was.
Q. How many outsourced products would you have been handling from 2005 through 2009?

A. I would say probably eight to 10 products then.
Q. And would there have been someone else handling other outsourced products during that time or were there a total of eight to 10 outsourced products being produced --
A. As far as -- that would have been the total, eight to 10.
Q. Okay. All right.
And for Digitek, was MPI the holder of the ANDA?
A. No. Actavis was.
Q. Actavis was.
A. Actavis.
Q. Actavis, thanks. Was it typical of the eight to 10 products, if you recall, were any of them -- were the ANDA's held by MPI?
A. Only one product was.
Q. Okay.
So it was more -- it was standard for the manufacturer to hold the ANDA?
A. Yes.
Q. I want to talk a little bit to the relationship of MPI with the outsourced product in this case, or the company Actavis. Actavis

dealt also with Bertek; what's the relationship -- what's the relationship between MPI and Bertek?

A. I probably wouldn't be the best to answer that, other than Bertek is an affiliate, I'm not sure if that's our correct legal term --

Q. Sure.

A. -- but they're an affiliate for Mylan.

Q. Do you know any more about the relationship between MPI and UDL?

A. UDL, Rockford; UDL, Sugar Land, Texas?

Q. UDL that the product Digitek would have been sent to, UDL, do you have any knowledge of that?

A. I don't, no.

Q. Well, am I correct in saying that if Bertek were to order the product Digitek, it would come through Mylan and go to Bertek?

MS. MCDONOUGH: If you know.

THE WITNESS: I would only be guessing. Probably, but I'm not sure how they had it set up, if it was a direct shipment from Actavis to Bertek or if they went through the distribution center. Most likely they went

through the distribution center, which is in North Carolina, Greensboro, North Carolina.

BY MR. MILLER:

Q. You're familiar with the terms COC and COA?

A. Oh, yes.

Q. Okay.

And what's the COC?

A. A COC?

Q. Yes.

A. Is Certificate of Compliance.

Q. And a COA?

A. Certificate of Analysis.

Q. And I'm correct in saying that if MPI were to order a lot of Digitek, then you with the title QA manager for outsourced product would review the COC and the COA in order to determine if that lot was going to be accepted; is that fair?

A. Right.

Q. But you don't have an understanding or do you know who would have accepted the COC's and a COA's for Bertek?

A. It probably would have been MPI, myself, if it would have been repackaged. Again,

I'm guessing because UDL, Rockford, is a repackaging site. Primarily that's what they do. They take product packaged in bottles from a distribution center and they repack them in the unit doses or something for pharmacies.

Q. Okay.

And just so I understand, under your title you do have a memory of or you were in a position where you reviewed COC's and COA's for Digitek, but what happened to the product after it was -- left your desk, if you will, that part you're not sure as far as if it went to Bertek or not?

A. The product itself?

Q. Right.

A. No. I just strictly would release the product.

Q. And in the time frame of 2007 through April of 2008, would you have worked with someone else as far as reviewing the COC's and COA's for Digitek or does anyone help you in this job or is it a one-person job?

A. I had one person reporting to me.

Q. Okay.

A. He helped -- it wasn't his primary

function but if there was a lot to do he would help if I needed help.

Q. Okay.

And who was that?

A. His name was Tom Conroy.

Q. Did Mr. Conroy have authority to approve a lot or would he still need to go through you to have that done?

A. No, he was trained to be able to release a lot.

Q. Okay.

So if you were away from the desk then Tom could review the COC's and COA's and release the lot just the same as you could?

A. If I was on vacation or out of the office, yes.

Q. Okay.

And then who did you report to at Mylan?

A. I reported to Chuck Koon, Charles Koon.

Q. What was Chuck Koon's title?

A. Director of -- it might have been compliance then, part of the quality assurance group, quality compliance let's call it.

Q. If in your position -- I'm sorry.
A. I'm sorry. Let me clarify, do you mean -- at what point in time who did I report to then? In that 2008 time frame?
Q. Exactly. I'm focusing on -- let's go for an 18-month period from the beginning of 2007 to mid-2008.
A. Okay, it was Chuck.
Q. Okay.
Who was it prior to Chuck?
A. Rich Bergen.
Q. And when did it shift from Rich to Chuck?
A. Rich retired, so Rich was when I started in 2005, '06, probably to the early part of 2007, I'm guessing. I don't recall.
Q. Okay.
So you're saying Rich Bergen held the position to 2007?
A. I think so.
Q. Okay.
And would you need to receive authority on individual lots from Chuck Koon when it came to releasing them after you reviewed a COC and a COA or was it something you would only

go report up to him if there was an issue with a particular batch?

A. That's correct. I could release on my own.

Q. Okay.

A. If I had questions, anything I needed to discuss with him, sure.

Q. Was there any SOP or guidance specifically on how you would contact him or deal with him or was it e-mails and kind of open communication?

A. It was open communication.

Q. Once you released a lot or a batch, were you involved at all with the customers where the pills were ultimately going to reside on the shelf? Did you deal with the customers of MPI?

A. No.

Q. So when a batch was released through your office, you had no idea where it was going?

A. No. I know they're released and they're in our distribution center and that's the last I know of it.

Q. Okay.

I assume there comes time to time when MPI would receive phone calls regarding

health concerns from either doctors, pharmacists or individuals who took the pills; does that sound fair, that statement?

A. I think what you're saying is a complaint; we call it complaints.

Q. A complaint; were you in any way involved in complaints that were received at MPI?

A. Yes, from a quality standpoint.

Q. What would be your involvement of complaints?

A. We have a group, they're called PSRM, product safety -- I can't remember what the acronym stands for, but it's our pharmacovigilance group. They receive the complaints, log them into a database and anything that is quality related, then the quality group would have to review or investigate if anything -- and we strictly were just following up on the investigations for the quality complaint side.

Q. All right.

When you say there was a database, you don't happen to know the title of the database, do you?

A. AERS, A-E-R-S.

Q. So you would not get involved with

the complaints that actually came in, it would be processed in the AERS and someone determined that it was a quality issue before it would get to you?

A. Right.

Q. Okay.

A. Right.

Q. And then would you make an entry into AERS after you were told that this particular complaint had issues with quality; would you -- what would you do from there?

A. It would depend on the situation, but in summary, yes, we would put in an investigation and investigate the complaint if it needed to be investigated and electronically signed off. It's an electronic system, electronically sign off on the investigation and then it goes back to the PSRM group, the pharmacovigilance group for their review.

Q. Okay.

Would your investigation become part of AERS or did it take on its own number and entity and stay out of the system?

A. My portion would stay within AERS. If it's something -- if it was a complaint having

to do with MPI, Morgantown, or something that was manufactured in Morgantown, that would be investigated and it would go into the investigation deviation database for Morgantown, and that has its own number.

Q. Specifically speaking it's a Digitek and we are not holding the ANDA and it's being produced off-site, what would -- would that change the procedures of the complaint?

A. Absolutely, actually because that's all that was handled by Actavis. The complaint was sent to Actavis by the PSRM group and they responded to it.

Q. So it would be a correct statement that if it was a complaint involving Digitek that it would or would not be entered in AERS?

A. It was entered in AERS, not by myself.

Q. Okay.

But if there was a quality issue, it would not be presented to you, it would be presented to Actavis or --

A. Right.

Q. -- would you still comment?

A. No.

Q. Give me, if you don't mind, just a quick synopsis of your education and training up to 2005 when you were employed by MPI.

A. Sure. I went to college at Michigan State, degree in packaging engineering, was employed by Owens-Illinois out of Toledo, Ohio as a quality engineer, did a lot of troubleshooting, traveled around the country, went to a lot of different sites where manufacturers, various manufacturers, food, pharmaceuticals, health care, anyone having issues on their lines packaging.

Owens-Illinois was a packaging company, glass, plastic, closures, bottles. So I would troubleshoot at the different sites. Transferred -- after two years from Toledo, transferred to the Vandalia, Illinois site in statistical process control. I was at that site probably a year which promoted and transferred to a site in Pennsylvania, Brookville, Pennsylvania.

I was the quality assurance manager at that site. Brookville primarily produced all the plastic child resistant closures for the pharmaceutical industry, the type you can't usually get off. They're hard to get off. Plastic vials

and bottles for the pharmaceutical industry. So I was responsible for all raw materials that came into the site and all finished goods that left the site -- not finished goods, they were packaging components that left the site.

From there -- so I was with Owens-Illinois for roughly 12, 13 years. And then I went to DSM Pharmaceuticals in Greenville, North Carolina. That would have been approximately 2000, and at DSM I was a quality assurance manager. I don't remember my exact title but it was similar to that for -- and I was responsible for all the orals and topical group, which means ointments, creams, tablets, everything that was manufactured at the site for orals and topicals. I was responsible for batch record review. My group reviewed all the batch records, reviewed investigations and released the product for DSM. And that is when I left there in 2005 and came to Mylan.

Q. Got it. So it's fair to say that the vast majority of your work experience is on the packaging side of the quality assurance; is that accurate?

A. You could say that. It was packaging

with a high emphasis on pharmaceuticals.
Q. The packaging of pharmaceuticals?
A. Right, but I also had to troubleshoot pharmaceuticals, so I was in a lot of facilities, the Eli Lilly's, McNeil's, everyone that had -- that used those components. So I was at their sites a lot.
Q. I guess what I'm trying to get at is you don't have any chemistry experience or laboratory experience?
A. Correct.
Q. All right.
I'm going to mark exhibit one and I'm going to call it M-1 since we have so many already marked on the Actavis side, so we can separate them because we'll be marking them concurrently tomorrow and that would be a mess.
* * *
(Whereupon, Deposition Exhibit M-1 marked for purposes of identification.)
* * *
BY MR. MILLER:
Q. Take a look at that and let me know when you're ready for questions.
A. Is there anything in particular you

want me to look at or the entire document?

Q. My first question is and take your time, is have you seen the document before in the past?

MS. MCDONOUGH: You may want to just look through the whole thing and make sure. It looks like -- I don't know if there are appendices or exhibits, I can't quite tell yet. If you are familiar with it, feel free.

THE WITNESS: I probably have seen the document and I say that because a lot of -- we call these supply agreements, a lot of supply agreements come across my desk since I am -- especially now since I'm writing technical agreements, a lot of supply agreements come across.

BY MR. MILLER:

Q. Would supply agreements come across your desk on your previous title of third-party products --

A. If I had been working on a quality agreement or a technical agreement and one existed, I would have seen one most likely.

Q. Okay.

If you take a look at, and the first

page for the record is Mylan 0032383 and I'm going to the third page, which is 0032385 and it states Supply and Distribution Sgreement. This Supply and Distribution Agreement ("Agreement') is entered into this 5th day of August 1999 by and between. Reading that, does it jog your memory on having specifically seen or worked with the distribution agreement for the product Digitek?

A. Well, I definitely can tell you we never worked with this agreement. This agreement would have already been established and in place. I'm not responsible for them at all.

Q. Okay.

A. I just used them for a reference if they exist when creating a quality agreement or technical agreement, make sure maybe some of the terms don't conflict, if there were terms in there.

Q. Fair enough.

That being the case it's probably best if we come back to this in a little while. So set that off to the side.

A. Okay.

Q. And we will -- we will come back to it. Most of my questions are going to be in

chronological order, so I'll probably come back and hit different topics at different times, and I don't mind, you can hand me the whole thing.

COURT REPORTER: Here you go.

MR. MILLER: That might be easier.

BY MR. MILLER:

Q. I'm going to mark M-2; have you seen this before? Take a look at that document and --

MS. MCDONOUGH: Do you have an extra one?

MR. MILLER: I do, I'm sorry.

* * *

(Whereupon, Deposition Exhibit M-2 marked for purposes of identification.)

* * *

BY MR. MILLER:

Q. Would you have seen this before?

A. No.

Q. For any reason? No.

A. This is the first time I've seen this.

Q. There's no, at least I don't recall seeing a date on it and I was trying to -- I was hoping you had seen it before but I guess not,

but if you look down at the -- it's titled, Guide for Handling Atypical Calls; are you familiar with the term atypical calls?

A. No.

Q. The second paragraph states: For product information calls received for redacted products, obtain the contact name, address, phone number and question, explain to the contact that someone from redacted will be returning their call, call redacted and relay the information. Document calls on product information log. Have you ever dealt with the term product information log at Mylan?

A. No, this -- I guess I shouldn't guess but this must be from our product safety group. They are the ones that collect the complaints, like I said earlier.

MS. MCDONOUGH: Just for the record, I'm not sure of this but it says at the bottom this is part of Bertek's patient assistance program, so it may have come from Bertek and just I believe as a point of clarification that Bertek stopped its distribution of Digitek back in '05. So this may be unrelated but I'm not positive.

BY MR. MILLER:

Q. Okay.

I appreciate it. It came from Mylan, the Mylan, it's document 00, Mylan 0033543. I'm going to mark Mylan 3. And I'll represent to you this is an e-mail from Chuck Koon to you, subject, remaining quality agreements needed; would this be the same quality agreement that we discussed just a while ago?

* * *

(Whereupon, Deposition Exhibit M-3 marked for purposes of identification.)

* * *

THE WITNESS: Uh-huh (yes) Yes.

BY MR. MILLER:

Q. All right.

They redacted apparently a few product names but you would agree that it's indicated Actavis Totowa's Digitek is a product that needs a quality agreement?

MR. TABER: Objection.

MR. MILLER: It's okay to answer.

THE WITNESS: Yes.

BY MR. MILLER:

Q. Do you recall this e-mail in particular?

A. No, I don't recall it in particular.

Q. Do you recall having conversations with Chuck Koon regarding the need to have a quality agreement with Actavis?

MS. MCDONOUGH: Probably a continuing objection to the phrase the need for a quality agreement until it's defined.

THE WITNESS: It's -- I agree with the need. There's an initiative -- at that time there was an initiative to put quality agreements, technical agreements in place with everyone, all of our outsource companies and as this shows, the other sites that were redacted, these are our, I would say, three sites here that were remaining -- that needed to have the technical agreements put in place. A technical agreement is the same as a quality agreement.

BY MR. MILLER:

Q. Okay.

What's the purpose of a quality agreement?

A. The primary purpose is to delineate

the responsibilities between the sites. For example, who's responsible for reviewing a batch record? Who would be responsible for the artwork that needs to be supplied, who -- complaints, who answers complaints, things like that. That's within a quality agreement. You don't get into the financial information that you might have in a supply agreement.

Q. Are you familiar with the term good manufacturing practices?

A. Sure.

Q. GMP?

A. Uh-huh (yes).

Q. Would identifying who's responsible for GMP issues is that at a typical item in a quality agreement?

A. It's not worded that way. The way it more -- it would be worded in a technical agreement is that a particular site must follow GMP guidelines, must manufacture with GMP guidelines, that type of language.

Q. As a quality -- as the individual who is, and correct me if I'm stating this wrong, who's overseeing quality assurance with a third-party product manufacturer, what

responsibility do you have, if any, to ensure that the third-party is producing the product within GMP?

A. Really my only responsibility at that time was the release of product. Quality assurance is more a release of product, the liaison between that outsourced company and Mylan, issues come up; I was the point of contact. If an issue came up, I would notify my direct -- my upper management.

Q. Would your office or you ever have been involved in such things as inspecting the third-party?

A. We -- auditing?

Q. Yes.

A. No.

Q. Are you aware that MPI would audit the third-party even if it wasn't your office?

A. Yes. We had an auditing group that also reported to --

Q. Are you aware of any specific audits of Actavis?

A. I believe there was an audit.

Q. Do you know when that was?

A. I don't.

Q. Are you familiar with the term 483 inspection?
A. Yes.
Q. Do you have any reason to be part of -- well, let's ask this question; Mylan, MPI produces a number of products themselves, right?
A. Yes.
Q. Okay.
Other than the eight to 10 products that are outsourced to third parties, how many products during your tenure, let's specifically, let's say 2007, if you know, were produced by Mylan?
A. How many different products?
Q. Yes.
A. Probably close to 100.
Q. Would you have any involvement in the quality department with those products that were produced there at Mylan?
A. No.
Q. If a 483 was conducted at Mylan, would you have any reason to review it or any involvement in the outcome or response to it?
A. You mean if a 483 was issued to Mylan?

Q. Yes.
A. No.
Q. As quality -- in the quality assurance department for third parties, would you have any reason to be involved in 483's of the third-party?
A. No.
Q. Was it the responsibility of anyone in the quality assurance department to maintain copies of 483's of third parties?
A. I don't know.
Q. I've seen e-mails that are to and from Suzanna Wolfe and e-mails that are to or from Ann Wolfe; is there someone else at the company or do you go by Ann sometimes and Suzanna?
A. No, there is an Ann Wolfe.
Q. Okay.
What's Ann Wolfe's title?
A. I don't know. She's in, oh, what do we call that group? She's in business supply logistics. She's in that area. I don't know Ann's title.
Q. Other than you, who would have reported or what offices would have reported to

Chuck Koon?

A. The auditing group and, let's see, at that time I believe that was just the auditing group and myself.

Q. Was there any routine or scheduled communication between your group, QA, and the auditing group?

A. No.

Q. Would -- so there was never any time when -- you do recall there was an audit on Actavis?

A. Uh-huh.

Q. But there was never any time when the quality assurance group at Mylan would have discussed the findings of the audit with the auditing group?

A. I don't understand your question.

Q. Fair enough.

Would there be any reason for the QA of third parties, yourself, at Mylan to interact with the auditing group at Mylan following an audit of a third-party producer?

A. Okay, myself, no, other than locker room gossip, there is no -- it's not discussed. Audits are really kept confidential.

Q. Okay.

I'm going to mark this as M-4.

* * *

(Whereupon, Deposition Exhibit M-4 marked for purposes of identification.)

* * *

BY MR. MILLER:

Q. Have you seen this document before?

A. No.

Q. It was produced to us by Mylan, I believe, from the custodial files of Mr. Koon, but I'll make the statement that it's -- I'll represent it is what it is, Actavis, Little Falls, New Jersey, August inspections summary.

Were you aware of an inspection of Actavis in August of 2006?

MS. MCDONOUGH: I may need just a minute to read this. Have you read it yet?

THE WITNESS: No, I haven't read this.

MR. MILLER: Would you like to review it?

THE WITNESS: Yeah, that would be great.

* * *

(Brief pause)

* * *

THE WITNESS: I'm ready.

BY MR. MILLER:

Q. All right.

Now that you've taken the time to read this document, does it come to mind that you perhaps have seen it?

A. No, I have not seen it.

Q. All right.

Are you -- were you aware that there was an inspection, FDA 483 at Actavis in August of '06?

A. At that time when I was performing the job duties then I don't believe I was aware of. After, you know, after the issue why we're all here today, then it became -- that I understood there were 483's issued.

Q. Now that you've read it, will you agree with me that it's observations, findings during an inspection that discuss GMP issues at Actavis?

A. Uh-huh, yes.

Q. And were you aware of the GMP issues at Actavis in 2006 and '07?

A. I was not because that responsibility more is -- it wasn't part of my job duties or responsibilities to be involved in that. That's more my upper management that was more involved with the compliance, the auditing of the sites. That wasn't part of my role.

Q. So you viewed your role as looking at the paperwork, the documents, the documentation of each individual lot to determine that it met compliance?

A. Right.

Q. And then take that lot and release that lot?

A. Yes.

Q. Okay.

I'm going to hand you what's been marked previously as Plaintiffs Exhibit 25, and it is -- I'll represent to you it provides a warning letter that went out to Actavis in February of 2007. Have you seen this before?

A. I believe I've read it at some point in time.

Q. Are you familiar with the term warning letter that results from a 483?

A. Sure. Yes.

Q. And would you agree with the statement that 483's don't typically come with a warning letter, that's kind of a step beyond the findings of the 483?

MS. MCDONOUGH: Objection, if you know.

THE WITNESS: Usually, yes.

BY MR. MILLER:

Q. Were you aware of this warning letter at the time it was received at Actavis back in February of 2007 or sometime close?

MS. MCDONOUGH: Do you want to take a minute to read it?

THE WITNESS: No, I know what this is. I don't know -- what I'm having difficulty is, I don't know at -- I know about all this now. I'm aware of it now, but at the time, I don't know at what point in time I did become aware of this. I definitely have seen some of these documents, was aware of the documents after we had the issue with the problem batch and the batches recalled. That's really when I, you know, became aware of all these documents. So I can't tell you at what point in time I knew about it.

BY MR. MILLER:

Q. When you say the problem batch; is there a specific batch in your mind that stands out whenever it comes to Digitek?

A. I thought that's why we were all here today.

Q. Were all batches recalled?

A. Now that I don't know.

Q. Okay.

What did you do in preparation for the deposition today?

A. Met with our attorneys.

Q. How many times did you meet?

A. Twice. I think twice.

Q. For how long?

A. Several hours both times.

Q. Were you shown any documents?

A. Yes.

Q. What documents were you shown?

MS. MCDONOUGH: I'll just step in and explain. We didn't show her anything you haven't been produced and we did pick out certain documents to show her and you've got some of them here, but, or probably there but we do consider that work product, but there's nothing

that the witness was shown that you don't already have.

BY MR. MILLER:

Q. Did you personally review any documents in preparation not being in the company of your counsel?

A. Yes.

Q. What documents?

A. I reviewed the investigation for, I don't know the batch number, 709 -- the particular batch, the batch that was recalled, 70924, I think. I reread that investigation.

Q. Did you have that investigation in your file at work or is it something that you received since the time of the investigation?

A. No, that's at work. It's within the batch.

It's part of the batch documentation of that batch, which is kept at Mylan.

Q. Okay.

Going back to what was previously marked as Plaintiffs Exhibit 25, the revised warning letter, I won't read the entire -- you're familiar with it now, just going back to the bottom paragraph where it starts out: The

significant observations included but were not limited to the following --

MR. TABER: Objection to the reading of the document and also the parts that don't relate to Digitek.

BY MR. MILLER:

Q. And number one, significant deficiencies were found in the operations of your firm's quality control unit and as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess. Do you see that?

A. Uh-huh.

Q. Is it important for a quality assurance personnel at Mylan dealing with a third-party producer, Actavis, who has received a warning letter to this -- with this language; is it important for you to know that --

MR. TABER: Objection.

MR. MILLER: -- in your job?

THE WITNESS: It's important for our department to know that. It wasn't my -- as I explained earlier, it wasn't part of my job

responsibility to get, if you want to say, into the nitty-gritty of the sites. It was to release products. If there were issues that came up, I reported to my upper management. It was quality assurance, upper management quality assurance. It's part of their responsibilities and decisions of investigating, if you say, issues at sites.

BY MR. MILLER:

Q. Of the eight to 10 products that were being made off-site, the third-party products, how many companies were making those eight to 10 products?

A. Probably six perhaps, five or six.

Q. Those six companies, Actavis -- how many products did Actavis make?

A. Two.

Q. Of those six companies, excuse my extremely non-technical term, would these types of issues make Actavis a problem child?

MR. TABER: Objection.

MS. MCDONOUGH: Objection, even you knew that was objectionable.

BY MR. MILLER:

Q. Is it more of a concern when a third-party producer has this type of warning

letter in the file than say a third-party producer who wouldn't have such a warning letter in the file?

A. I would say it would be more of a concern, but understand that the pharmaceutical industry is heavily regulated by the FDA and are inspected all the time. Observations are written all the time, the FDA never comes out of a site without writing up observations. It's part of their job is to write up observations. So it's not unusual to find sites with lots of observations written.

Q. Lots of observations may not be unusual, but would you agree with the statement a warning letter is unusual?

A. I don't want to use the word unusual. A warning letter might be more significant.

Q. Okay.

And would a company ceasing the production of a product even be more significant than that?

A. Yes.

Q. Do you recall dealing with warning letter issues with the other five or so third-party producers?

MR. TABER: Objection.

THE WITNESS: I have to think who they were. Not that I recall.

BY MR. MILLER:

Q. Did MPI have sales reps?

A. Yes.

Q. Do you know if MPI sales reps would have marketed Digitek or would Actavis sales reps market Digitek?

A. I have no idea.

Q. Fair enough.

MR. TABER: Off the record for a moment.

VIDEOGRAPHER: The time is 12:29; we're going off the record.

* * *

(Brief pause)

* * *

VIDEOGRAPHER: The time is 12:29; we're back on the record.

BY MR. MILLER:

Q. Who is Patricia Latzo?

A. Trish Latzo is now our vice president. She might be senior vice president of quality assurance.

Q. So Chuck Koon would report to her?
A. Yes.
Q. And how long has she held that title?
A. Probably -- she's had a series of promotions lately in the last three years. So she's been at least vice president probably the last three or four years.
Q. Okay.
So is it fair to say that since 2000 -- the beginning of 2007 the basic structure hasn't changed as far as you reporting to Chuck Koon, Chuck Koon reporting to Ms. Latzo?
A. There was a slight change. When I reported to Chuck, he reported to Mike Adams, Mike Adams reported to Trish --
Q. Okay.
A. -- Latzo.
Q. What was Mike Adams title at that time?
A. I don't know if he was senior director or vice president of quality assurance. It wouldn't have been vice president. It must have been senior director of quality assurance.
Q. And Ms. Latzo was vice president of quality assurance?

A. Yes.
Q. And that's vice president of quality assurance across the board. That's not a third-party thing; it's a Mylan quality assurance?
A. Right. Right. We've had a lot of changes, so I apologize because it's hard to keep everyone straight.
Q. I want to mark M-5. Take a look at that, please. The warning letter was previously marked.

* * *

(Whereupon, Deposition Exhibit M-5 marked for purposes of identification.)

* * *

BY MR. MILLER:
Q. Have you seen this before?
A. Yes.
Q. Do you recall the topic?
A. Well, in reading this I see that it was a request for an investigation from Dan Bitler at Actavis.
Q. Did you -- who did you typically deal with at Actavis?
A. Dan Bitler most of the time.

Q. Who else would you have dealt with?
A. Actually probably Dan. I didn't have many conversations but when I did they would have been with Dan.
Q. And just so I get the picture right, you weren't involved in the lot or batch being ordered, but if a lot or a batch were to be ordered and delivered, then that's when you would review the COC and the COA and if there were any issues, that's why you would talk to Dan?
A. Yes.
Q. Okay.
So it would be seamless, or I say seamless, it would take place without communication if the lot or batch was ordered, delivered, the COC, COA were within your specs, then it would move on without needing to communicate with Dan at all?
A. If I had all the documentation, yes.
Q. Okay.
And this case -- it's probably been produced, but there are so many documents I haven't found it yet, but it starts out like most e-mail chains, we have to go to the bottom to get it in the right order, and where it says Dan at

the very bottom, I see there is a deviation for Lot 60992A1 deviation of 00SN-0014. Can you send me a copy of this? Regards, Suzy Wolfe. You agree that that's a request from you to Dan?

A. Yes.

Q. How did you come to learn that there was a deviation in that particular lot?

A. The documents that they send, the COC's, the Certificate of Compliance, there's a section on the compliance, the certificate form, that states whether there were any deviations during the manufacturing of the product. This particular deviation 00SN was noted on the certificate of compliance, that there was a deviation with that lot, 60092.

Q. Would you agree with the statement that if a deviation was observed in the testing at the third-party producer, it was resolved before it came to you; it didn't come with a deviation in the COC or the COA, it just commented on the fact that there was one; is that correct? If that makes sense.

MS. MCDONOUGH: Objection, vague.

THE WITNESS: Do you mean was

there one in the past? Maybe you could rephrase it.

BY MR. MILLER:

Q. You didn't catch something that they didn't catch?

A. I think what you're trying to say is was the deviation closed before it was received at our --

Q. That was beautiful, yes.

A. That's my job. Yes, it was closed.

Q. Thanks. And then we see Dan's response: Suzy, we do not send copies of documents, batch records, investigations, et cetera, to customers especially where we own the filing. You are welcome to come to our facility and review documents or I can send you a brief summary of the investigation via e-mail. Please let me know what you prefer. Dan. Did I read that correctly?

A. Yes.

Q. And my question is, is that -- was that -- did that language comport to what you understood the agreement to be with third-party producers, that he wouldn't provide that information to you?

A. Some do. Some who own the ANDA are very, very protective -- the ANDA, are very, very protective of their documents, will share very little of it because it's their product. They own it. This is not unusual for someone to provide me a summary.

Q. Did you ever take him up on his offer to go over and inspect the lab?

A. That's not what he's volunteering here.

Q. Well, all right, you're correct, hang on, let me make sure I state it right. Did you ever take him up on the opportunity to go over and visit his facility and review documents?

A. No. I did not.

Q. All right.

And then it says: A summary would suffice and if you could please note that it's actually resolved and closed as well. Thanks so much. Regards, Suzy Wolfe. As we sit here today, do you have a memory of receiving that document indicating that this deviation was closed?

A. This specific one, I don't recall specifically.

Q. Do you recall having other issues

with deviations on lots of Digitek?
A. Yes.
Q. What type of deviations would you typically see?
A. The ones that -- the ones that I remember and it's correct, it's not typical and atypical was a label lifting issue that we had. Actavis had a label lifting issue where the label around the bottle was starting to lift off on either end.
Q. Called flagging?
A. Flagging, yes. That was on a particular lot, which actually extended -- there were several lots that and actually we found it throughout the industry, various other different manufacturers were having the same issue with the label lifting, flagging.
Q. Would you ever talk to Dan Bitler on the phone or was the majority of your communication via e-mail?
A. There were a few conversations on the phone, brief.
Q. Do you have any type of log you keep on phone calls or is that something you wouldn't do?

A. No. I have a daytimer on my desk and if there was something I needed to remember, perhaps there was something in our conversation I needed to find or look up, I would have jotted something down but that's it.

Q. I'll mark M-6. Do you recall seeing this?

* * *

(Whereupon, Deposition Exhibit M-6 marked for purposes of identification.)

* * *

THE WITNESS: Yes.

BY MR. MILLER:

Q. If we go back to M-3 real quick, it talks about needing quality agreements with Actavis back in January 30 of 2007. Will you agree with me that this is a contract request form?

A. Yes.

Q. And by you to Actavis, were requesting a quality agreement?

A. It was by me to -- it's not to Actavis. This is an internal document to our legal group.

Q. Okay. Fair enough.

And this is -- okay, so your request to the legal group in May of '07 regarding a quality agreement with Actavis?

A. Can you repeat that?

Q. Well, it's a contract request form from you to the Mylan legal department regarding a quality agreement with Actavis?

A. Yes.

Q. And you agree that it was in mid-May of '07?

A. Yes.

Q. Well, I guess my question is, we've discussed the e-mail from January 30 of 2007 stating that a quality agreement needed to be established with Actavis, but do you recall or is there a reason why it's taken until May before a request is out?

A. Well, let me explain what this form is. The quality agreement is drafted usually by myself and then once it's ready for legal to review, you fill this form out. And what this is doing is asking legal to put it in the queue as a project for an attorney to review. So I may have written the quality agreement months prior to this, but when I was ready to submit it to legal

then I submit this form and they assign it to an attorney to review and it's given a project number.

Q. Fair enough. That's what I was looking for.

How much of your time is spent on drafting quality agreements or getting quality agreements signed; is that a large portion?

A. Now or back then?

Q. The time frame 2007.

A. It was probably 40 percent of my time.

Q. And then the other remaining 60 percent of your time, how much of that would have been reviewing COC's, COA's for individual lots?

A. Primarily most of the rest of the time was reviewing documentation.

Q. So those are your two primary functions?

A. Yes.

MS. MCDONOUGH: Would this be a good time to just take a few minutes of a break or --

MR. MILLER: Yeah, it certainly is. We'll take a break.

VIDEOGRAPHER: The timing is 12:52; we're going off the record.

* * *

(Short break taken)

* * *

VIDEOGRAPHER: The time is 12:56; we're back on the record.

BY MR. MILLER:

Q. Ma'am, I'm going to hand you what I have marked Exhibit M-7.

* * *

(Whereupon, Deposition Exhibit M-7 marked for purposes of identification.)

* * *

MS. MCDONOUGH: Thank you.

BY MR. MILLER:

Q. Have you seen this e-mail before?

A. Give me a second to read it first. Okay.

Q. Do you recall seeing this in the past?

A. Yes.

Q. The only thing I really want to refer to is the very top line there. It says -- well, it's an e-mail from you; correct?

A. Yes.
Q. To Chuck Koon and this is Mylan document 0032473 for the record. The subject is regarding forwarded Digitek docs: Yes, these would be fixed batches or batches with the new labels. No batch records for Digitek, only redacted. They send just the COA and COC. Suzy. Do you agree that this is discussing the flagging issue that we talked about?
A. Yes.
Q. What I want to address is the comment they send just the COA and COC, and those are the two documents that we identified earlier; correct?
A. Uh-huh.
Q. Would other companies send additional documents or less documents?
A. Like I stated earlier, there are some that do and some that don't.
Q. Isn't that governed by some SOP or document internal to Mylan or is that governed by documents at the third-party?
A. The SOP internal to Mylan states that at minimum you need C of A, C of C, possibly it could also receive batch records, miscellaneous

documents.
Q. So you don't receive batch records from Actavis regarding Digitek?
A. No.
Q. Other than the COA's, COC and batch records, what, if any, are some of the other documents that you received from third-party manufacturers?
A. Investigations that would have been related to a particular batch.
Q. And you would agree that Actavis did not send investigations of a particular batch as we saw in the previous e-mail?
MR. TABER: Objection.
THE WITNESS: The previous e-mail, it showed that I requested it and they sent a summary of the investigation.
BY MR. MILLER:
Q. We can go back and look at it but do you agree that Dan Bitler informed you that he wasn't going to send the investigation?
MR. TABER: Objection.
THE WITNESS: He said like I just stated, he said he would not send the investigation but he would send a summary of the

investigation.
BY MR. MILLER:
Q. Fair enough.
Do you know as you sit here what SOP would be at Mylan that directs that COA's and COC's will be sent at a minimum?
A. I don't know the specific number. The title would be something of the effect of releasing batches for outsourced parties or something of that sort.
Q. I'm going to mark Exhibit M-8. If you would take your time to read that, I would appreciate it.

* * *

(Whereupon, Deposition Exhibit M-8 marked for purposes of identification.)

* * *

BY MR. MILLER:
Q. And this is Mylan document 0032479, an e-mail from yourself to Rebecca Pinnell, July of 2007; do you recall seeing this document or the topic?
A. Yes.
Q. Who is Rebecca Pinnell?
A. Pinnell.

Q. Pinnell, I'm sorry.
A. Becky worked in our group at that time.
She helped back me up or was my replacement when I was out a couple times, she was filling in for me.
Q. Okay.
So we discussed a gentleman by the name of Tom Conroy. Would she have done the same functions as Tom Conroy? The same title?
A. No. Becky actually at that time, I believe, was an associate director and she was trained as well to release batches. There was a point in time and I don't remember the exact dates, there was a restructuring of our group and I reported to her just for a couple months before I went to another position. So she resumed my duties, she was in our group.
Q. And we'll go to the end of the e-mail to get the beginning of the topic chain and it's -- where it says: Hello Suzanna, I have in order due to ship to UDL next week for Digitek .125 milligrams. The following lots are available to ship but I will need to know if UDL parameters are met. Do you have the UDL parameter listing

for Digitek? I'll stop there and my question is; did you maintain documents for UDL regarding parameters or specifications?

A. What she's asking -- no, we didn't maintain documents.

Q. What was she asking you?

A. What she's asking is for us to review the C of A that came with a particular batch that we, MPI, would have released. So she's asking for us to review the Certificate of Analysis and does it meet UDL specifications. UDL has tighter specifications, disso and assay here; these limits are tighter than what Actavis's parameters are.

Q. Okay.

I'm going to take that in two different parts. One is she's asking about lots that you would have already released to UDL?

A. We don't release them to UDL. Lots -- it's confusing, lots that we would have released for distribution, they're in a release status down at the distribution center.

Q. But are these distributions for UDL?

A. They're distributions for the world. They can go to anybody.

Q. Okay.

Well, that brings me back to the question then it would be your understanding that UDL doesn't have a counterpart that's equal to you, UDL doesn't have someone that reviews COC's and COA's?

A. I don't know.

Q. Okay.

But you do know that lots down -- lots that you have accepted could potentially fill UDL orders?

A. Yes.

Q. Okay.

And were you aware that UDL had parameters different than those set by MLI or SOPs at Actavis?

A. Yes.

Q. And so then is it fair to say that you would operate under those tightened specifications because obviously you don't know if it was going to UDL or Bertek or MPI, so did you use the tightened specs yourself?

A. No.

Q. Okay.

So if -- looking at an assay, for

example, would those numbers be on the COA or the COC?

A. None of these numbers are on the C of A or C of C. These -- and if you're referring to the bottom of this, yes, this assay of 98 percent to 103 percent, disso, 90 to 60 minutes, that's UDL's parameters. UDL has their own specifications for Digitek.

Q. Okay.

A. So in essence what they're asking here is, hey, only send us lots that would meet this. If they're anything outside this, say the assay was 97 percent; we don't want it. It's well within specifications of Actavis's specifications. UDL just has a tighter, tighter spec. So they only want specific batches.

Q. Were you the gatekeeper that would determine if it was inside the tighter parameters or would someone else determine that?

A. Well, that's what she's asking here. She was asking me to do that. I always try to push back to UDL because they could do the same thing I was doing as well, take Actavis's C of A, does it meet their specifications. If it does, they can receive that batch. That's all this --

that's all she's asking for here. She, being Connie Hatcher.

Q. Well, if that information is not included in the COC or COA, is there documentation in the packet that comes to you that has the assay findings from Actavis?

A. The assay and disso is on the C of A.

Q. Oh, okay.

A. But it's Actavis's specifications --

Q. Right.

A. -- which are let's say this wide (indicating).

Q. Okay.

A. UDL has specifications this wide (indicating). They are tighter.

Q. I'm with you now.

A. Okay.

Q. If a COA came down to you for a specific lot and it was outside of UDL's parameters but inside of Actavis's parameters, what would your action be, if anything?

MR. TABER: I'm sorry. Could you clarify which parameters you're asking her about? Are we just talking about assay and dissolution?

MR. MILLER: Yes.

BY MR. MILLER:

Q. The assay, typically the assay is what, if you know, for Actavis?

A. I don't know. I don't recall.

Q. Would you agree we've defined that they are broader limits than the ones requested by UDL?

A. Yes.

Q. And so my question is regarding assay as it's defined in this e-mail, if you, the reviewer of the COA were to see an assay value for a particular lot that were outside of the parameters UDL is requesting, but inside the parameters of Actavis, what action would you take, if any?

A. When I -- to release the batch for MPI, we use Actavis's specifications and then the batch is released. It's down at the distribution center. UDL will pull from those batches that are already released and they'll send an e-mail saying I want this particular batch. Is it okay to send? Their parameters are tighter like we discussed, so we take a look at the C of A and tell UDL they meet your specifications, you can

have it. If they don't meet UDL's specifications, then they'll pick another batch. It's still good product. It's still viable product, just not for UDL.

Q. I totally understand. But I guess my question is, is there any specific action that you take as you're reviewing the COA if you see that it falls outside of the parameters of UDL but inside the parameters of Actavis?

A. If I'm reviewing it for UDL?

Q. Yes.

A. I respond back to UDL and say it's outside your specs. You don't want this batch.

Q. So you know if a lot batch comes in that's being inspected or accepted for UDL --

A. No.

Q. -- if it's not?

A. No.

Q. Okay.

Then how would you know if you needed to know what parameters to use?

A. I get an e-mail from UDL.

Q. After the acceptance of the COA or prior?

A. After.

Q. Then wouldn't it already have been released or they send the same release back to you and say this is a UDL; I need the parameters to be tighter?

A. No, well, back up. I release the batch --

Q. Right.

A. -- for MPI, for Mylan and it's down at the distribution center. It's a released batch. UDL draws from those batches. They will pick a particular batch, something that I've already reviewed, I've already released, it's good.

Q. Right.

A. It's a good viable product. UDL picks batch X and says does this meet our specifications, like she's asking for here. Is the assay and disso within these specs? It either is or it isn't. If it is, we say, yes. So UDL takes -- I don't know how much they take, they might only take a pallet, they may take a carton, I don't know. But they'll take a quantity from that batch. The rest of that batch gets shipped. It's shipped to whomever, but it's good, viable product. UDL for some reason has a

tighter specification. They only want this particular product.

Q. Okay.

A. Does that make sense?

Q. It does make sense and I'm with you. Then is it correct to say that if UDL is going to take a portion of a lot, any time that UDL has identified a lot or portion of a lot that they want to draw from, that they have to come back to your office and say, is this particular lot within our parameters?

A. Yes.

Q. And is that typically done at your desk? Is that one of the functions that you have?

A. At that time I did that for them.

Q. When you say at that time, you mean the entire time that you were QA of third parties?

A. Right.

Q. Would Mylan have any SOPs, MLIs or anything of the like that would address the tightened parameters by UDL?

A. Not Mylan, MPI.

Q. Any entity of Mylan?

A. I don't know about anybody else.
Q. Which leads me to Mylan 9. Not that one because I've highlighted it. Take a look at that document, please.

* * *

(Whereupon, Deposition Exhibit M-9 marked for purposes of identification.)

* * *

BY MR. MILLER:
Q. And this is document 0027853, and I'll represent it's titled UDL Laboratories, Inc. Memorandum; and is it fair to say this is a document that reflects exactly what we've just went through as far as UDL requesting information of out of spec assay?
A. It's not out of spec assay.
Q. Out of tightened parameters assay?
A. That's not correct either.
Q. How would you say it?
A. They're within specifications; they're UDL's tightened.
Q. They're outside of UDL's tightened specifications?
A. We acknowledge that the assay result is outside -- yes, that is correct to say that.

Q. Within safety parameters but not within the tightened parameters of UDL?
A. Correct.
Q. And this is to Mylan Quality Assurance, so would that be Mr. Koon at this time?
A. I don't know who this was sent to or directed to in quality assurance. I'm copied on it obviously.
Q. Was there a standard form for when UDL requested a lot to say inspect this lot to see if it's within our parameters?
A. No.
Q. No? Do you have a sense for what percentage of the product was branded UDL versus Bertek?
A. UDL versus Bertek?
MS. MCDONOUGH: Objection, as to what time period and I'm not sure that there's foundation for that.
BY MR. MILLER:
Q. In September of 2007 at the time of this memorandum, what percentage of the product, Digitek, went to UDL versus went to Bertek?
MS. MCDONOUGH: And just

objection, I think as we noted before, I believe Bertek stopped any distribution in '05.

MR. MILLER: I'm a slow learner.

MS. MCDONOUGH: That's all right.

BY MR. MILLER:

Q. If you understand the question, at this time frame, do you have an idea of what percentage of the tablets would have gone to UDL versus Mylan?

A. No.

Q. And the third page of this document, although it's been cut off, I believe it's Mylan 0027855, is in fact a copy of a Certificate of Analysis; correct?

A. Yes.

Q. For this particular lot. And the typical form that you would have seen it in, but this is not the typical paperwork that you would have received to release a lot batch?

A. Actually, no, the last two pages would have been what I would have received. That was typical for a C of A.

Q. Oh, yeah, I wouldn't notice it but

the second page is a Certificate of Analysis?
A. It's just a cover page for the third page.
Q. But you would agree that you would also receive, which is not here, a Certificate of Conformance?
A. Correct.
Q. I'll mark M-10.

* * *

(Whereupon, Deposition Exhibit M-10 marked for purposes of identification.)

* * *

BY MR. MILLER:
Q. Take a look at that. What is this document?
A. This is a batch record.
Q. Would you agree it's a typical batch -- a typical batch record?
A. For Actavis, yes.
Q. For the product Digitek?
A. Yes.
Q. And the first page here, what's the significance of the barcodes, if I'm using the right term?
A. I don't usually see this. This is

applied by -- all of our documents are electronically scanned --

Q. Okay.

A. -- and electronically filed. So the scanning group attaches these barcodes. I don't know what they're for, to identify it somehow.

Q. Oh, so that's something that you typically --

A. No.

Q. -- would not see. Okay. But this Mylan cover letter, the second page, Mylan document 00263221 is the typical cover page that you would get?

A. Yes.

Q. And was it typical that you'd get four lots listed at one time if that's what I'm seeing?

A. Actually, it's not what I'd get, it's what I create.

Q. What you create, okay.

A. I created this page.

Q. That makes sense, yes, okay. This is ultimately what -- when you release the lot, this is what you would create, put the cover letter on top of it?

A. Yes.
Q. Okay.
And what you're stating is, the following products have been approved for release and distribution pending acceptable incoming inspection at the Greensboro distribution center; is that correct?
A. Yes.
Q. Would follow-on testing be conducted -- or actually, strike that.
Would follow-on review of the documents for approval be done at the Greensboro distribution center as far as you know?
A. Would follow-on?
Q. Well, it says pending acceptable incoming inspection; what type of inspection, if you know, is completed at Greensboro?
A. Yes, Greensboro performs a visual inspection of the product at their site.
Q. Visual of -- do they open up bottles and visually inspect the tablets, do you know or is it visual inspection of the bottles and packages?
A. Visual inspection of the bottles and packages.

Q. But they would not review any -- if you allow me to use the term, laboratory GMP issues or assays, test or --

A. No.

Q. No, okay. And you finish up with the line: The analysis records and Certificate of Conformance were reviewed and found to be in GMP compliance; did I read that correctly?

A. Yes.

Q. And you were the only person at Mylan who for this particular lot and most lots who would accept it as far as GMP issues go with each lot?

MS. MCDONOUGH: Objection, vague. I'm not sure what you mean.

MR. MILLER: It was.

THE WITNESS: I was going to say that before she did.

MR. MILLER: I was thinking that.

THE WITNESS: She beat me to it.

BY MR. MILLER:

Q. That was your primary function as the QA third-party producer at Mylan was to do just

that, that's your function is to determine that they would be found to be within compliance of GMP's?

A. The records. The documentation?

Q. Yes.

A. Yes.

Q. And the next page, again, the barcodes that you didn't generate?

A. No.

Q. All right.

And then it goes to a quality assurance inspection form for distribution centers -- excuse me, what exactly is that?

A. This is the form that the distribution center uses when they inspect product, on incoming they fill out this form.

Q. So you didn't fill out the form?

A. No.

Q. What is the information -- okay, so this is the lot coming to Mylan and it goes through some other department or office to gather this information before it gets to you?

A. I see documentation; this is the physical product. The product is shipped down to Greensboro, North Carolina.

Q. Oh, okay.

So Greensboro -- all right, the product goes right to Greensboro. You get the paperwork, you okay it, now that it's sitting in Greensboro, it's clear to go somewhere else?

A. Yes.

Q. And as it's sitting there in Greensboro, someone fills this information out and it gets put on to the COC, COA before it gets sent to you?

A. No.

Q. Okay.

A. Close. The C of A and C of C have already -- usually have already been sent to me.

Q. Got you.

A. This documentation, once the quality group down at the distribution center completes this, they send it to me and I add it to, so it all becomes part of the batch record.

Q. Okay.

So this quality assurance inspection form would come to you, you would look to see what lot it is and marry it up with the COC and COA for that particular lot and then it becomes a document?

A. Yes.
Q. Okay.
And down at the bottom, that highlighted box at the bottom, it says QA disposition, batch record review, there's a check mark, yes, would this be your handwriting inside this box?
A. No, I have nothing to do with this form.
Q. Okay.
Would you agree that to the right of that where it says if yes, reviewed by; is that your signature?
A. No. That is Miss Janet Kinsley, down here at the bottom. what she's saying is, off to the left where it says batch record reviewed, yes, NA, she's checked marked the yes and if yes, who was it reviewed by --
Q. Okay.
A. -- and she's saying it's reviewed by S. Wolfe.
Q. And what's Mrs. King's title?
A. Kinsley. Janet Kinsley --
Q. Kinsley, I'm sorry.
A. -- is her name.

Q. Yes.
A. She's quality assurance. I don't know her title.
Q. All right. Fair enough.
And again, there's another barcode that's added after your -- after you've reviewed the document; correct?
A. Yes.
Q. All right.
And then we go to a Certificate of Conformance. Is this form something that was created by Actavis -- the blank template or was it something that you provided to Actavis or Mylan provided to Actavis?
MS. MCDONOUGH: If you know.
THE WITNESS: I believe when we first started doing business with Digitek products, we -- they asked what would we like to receive and we, I believe we did supply this language to them, to put in as a standard template.
BY MR. MILLER:
Q. And the next page is the title page for the Certificate of Analysis but not the Certificate of Analysis itself; correct?

A. Correct.
Q. All right.
And if we turn to the Certificate of Analysis, we see -- do you agree that it's a fair statement that this is the quality control lab at Actavis; it's their findings when doing routine testing for the product?
A. I'm assuming that. I don't know.
Q. All right.
MS. MCDONOUGH: Objection to the phrase, did you say quality assurance lab? I'm not sure if that's accurate.
MR. MILLER: All right, quality -- the quality control system at Actavis?
THE WITNESS: I don't know what they call it, quality control or quality assurance, but it's from the lab.
BY MR. MILLER:
Q. Fair enough.
And then -- so you don't have any reason to review the data on this sheet. It's your -- do you go through and determine if each one of these is within the specs?
A. Yes.
Q. You do?

A. Yes.
Q. And you do that by the limit, so it's the third column on the right, so you take the limit that they've put down and make sure that the second column matches or is inside the limit?
A. Yes.
Q. Okay.
And then when you do that -- so the only reason, the only time you would ever go in here and look at the Certificate of Analysis for something outside of the limit is if you -- there's been some type of investigation for out of specification; would that be one reason you would go in here and look to see if there was data outside of the limits?
A. We always are looking for data to be inside the limits --
Q. Right.
A. -- when we're reviewing it to release.
Q. Well, okay, I'm going to try to come up with a better question here.
By way of example -- well, the assay, which is the fourth or fifth col -- row down and this one, you see where it's 98.3 percent?

A. Yes.
Q. And then you go to the right and the limit is 90 to 105 percent?
A. Right.
Q. So we'd agree that that's inside the limit; if you were to find out from UDL that they wanted some portion of the product from this lot, would you go back and reprint this document in order to see if the assay was inside that tighter limit that we discussed or is there a file you keep for each lot? How do you regenerate this to determine the UDL's request?
A. Well, this is electronic, like I explained earlier, so I have the access to go online and pull the batch record up electronically and would print out this page for UDL and then just verify that, in this example the assay is within specification.
Q. So there's a software you use where you go online and open up a secure software and you can type in the lot number and the information pops up?
A. It's an application. It's whatever is used to create this.
Q. You don't know what the application

is called?
A. I don't. I'm not familiar with it.
Q. Okay.
A. It's document retention really is what it does. It retains all the documents electronically.
Q. I need to mark this as M-11. I'm going to hand this do you.

* * *

(Whereupon, Deposition Exhibit M-11 marked for purposes of identification.)

* * *

THE WITNESS: There's two here.

MS. MCDONOUGH: Thank you.

BY MR. MILLER:
Q. Do you recall seeing this document before?
A. Yes.
Q. Is this the inspection that you indicated you reviewed -- the document that you reviewed on your own prior to this deposition?
A. Yes.
Q. And how did you go about obtaining a copy, did you use that application online that we

just discussed to get a copy?
A. We have a -- we have a copy of all the documentation that was supplied to our legal department when it was all requested from legal and we have -- all the original documentation came back to us in a box --
Q. Okay.
A. -- labeled Digitek, Actavis, this batch, so that's where I got it from.
Q. Other than what is -- would you agree this is the -- what's the proper term for this document as a whole? Not just this lot, on every --
A. Batch record.
Q. Batch record, okay. Would you agree that this is the batch record that you originally received for lot 70924?
A. Originally received, meaning?
Q. Back when -- would there have been -- I don't know; would there have been a batch record for this particular lot that you would have received prior to this?
A. Well --
MS. MCDONOUGH: Objection, I mean the document looks like it contains many

different pages, some of them from different dates but then compiled to one record. So I think when you say received at that time, it may not be quite accurate.

MR. MILLER: I guess that's my -- that is my question.

BY MR. MILLER:

Q. How did all these pages -- did all these pages come to you at one time?

A. No.

Q. Explain to me how the documents came to you in your role as QA of third parties.

A. Okay. The fourth page back -- the Certificate of Conformance from Actavis --

Q. Right.

A. -- it's titled, that document as well as the Certificate of Analysis, the next page, would have come to me. I don't recall if the investigation came to me at that time when those two did or I had to request it. But definitely the C of A and C of C would have come to me at one point in time and then Janet's -- or the distribution center inspection report that we talked about that, that would have come at another time, point in time, and then I would

have put all the documents together as well as my release memo.

Q. All right.

Is it a fair statement to say then when there was an incoming document, but at some point in time you released the lot based on completed batch record, is this -- all these documents in Exhibit 11 as it's marked, does it represent the completed batch record that you would have released that lot with?

A. Yes.

Q. Okay.

Is this entire document what you would have uploaded, if that's the right term, into the application where all the batch records are stored online?

A. The batch record group would have uploaded this.

Q. Okay.

But you agree this is the document that would have been uploaded?

A. Yes.

Q. Did you ever go back into the application and download what was uploaded in order to see either for preparing for this

deposition or for any reason since you reviewed all the documents?

A. No.

Q. And if we go to the page after the Certificate of Analysis titled Investigation of Deviation Report, it's Mylan 002283, you'd agree that this is nonstandard, the only time you would receive this type of report is if, in fact, there was an investigation with some type of specification issue with the lot?

A. Right.

Q. And then what is your -- setting aside this particular batch, what are your standard procedures when you receive a batch record that has an investigation report?

A. Review the investigation, if I would have any questions about it, contact Mr. Bitler and discuss with him if I would have any questions or if I needed to see something further. If I was satisfied and felt everything was within compliance and within specification and the investigations were done according to procedure, then I would release the batch. If I had a concern with any investigation or a question, I would also talk to my management, my

boss.
Q. Do you recall specifically having conversations with Mr. Bitler regarding this investigation of lot 7092481?
A. I don't recall specifically, no.
Q. Does the -- will you let me use the -- you agree with the term the issue was double-thick tablets?
A. Yes.
Q. With this particular lot?
A. Yes.
Q. Do you recall having any particular concerns with double-thick tablets that were found in a lot of Digitek?
A. What do you mean by concerns?
Q. Well, as the quality assurance representative for Mylan of third-party producers, had you ever seen in the past lots that had double-thick tablets in them?
A. I had never personally seen any. I know that it can happen.
Q. Okay.
You know that it can happen and you haven't personally seen them. My question is have you ever received batch records in which there

was an investigation as to the batch record that said we found double-thick tablets --

A. No.

Q. -- in this lot?

A. No.

Q. Is the word concern, I'm not sure what the question is about the word concern. As a quality assurance representative for Mylan of third-party producers, can you think of any concerns with double-thick tablets?

MS. MCDONOUGH: Well, objection, I guess now I'm not sure what you mean exactly. With this particular lot or a specific time frame or in general, double-thick tablets or what type of concern do you have in mind?

MR. MILLER: I'm asking for concerns, if you understood the question, it's okay to answer.

THE WITNESS: The way I interpret a concern is anything that would be out of specification. If it's double-thick, then obviously the thickness is outside of specification.

BY MR. MILLER:

Q. Okay.

And would the batch record indicate what action you took to follow up on this, whether you had phone conversations with Mr. Bitler or whether you did any personal investigation on this?

A. No, if there was any documentation, it would be in here.

Q. So --

A. It would be in here.

Q. Do you agree that if you would have done -- I mean it is an option to -- you said an option would have been to call Mr. Bitler and discuss it; would that phone conversation had it occurred been logged?

A. No, most likely not.

Q. Okay.

What other actions can you think of that you potentially -- in your role, what options did you have as far as digging further into this investigation did you have?

A. Well, discussing it with my supervisor --

Q. Uh-huh.

A. -- at the time.

Q. Do you recall discussing this issue

with your supervisor?
A. Yes.
Q. And that would have been Mr. Koon?
A. Yes.
Q. Okay.
And what conversations do you recall between yourself and Mr. Koon?
A. I showed him the investigation report. He read the investigation report. We discussed if we both felt that we were comfortable and confident with how the investigation was conducted, and how the batch ultimately was handled and the CPA, that's Corrective Preventative Action, the CPA that was put in place.
Q. Did all your knowledge regarding this investigation come from the documents that are attached to this batch record?
A. I will say yes because I can't -- if I did talk to Dan, I can't recall if I had a conversation with him.
Q. But you don't recall seeing any other documentation from any other source?
A. No.
Q. Do you know if Mr. Koon reached out

and obtained any documentation beyond this batch record?

A. I don't believe he did.

Q. You see in the upper right hand corner the handwritten part, would you agree that it says page one of 67?

A. Yes.

Q. And I'll represent to you that there's not 67 pages here. We can go through and see which ones are not here. Do you recall ever having any concerns about seeing a complete 67-page document?

A. I remember that this was a lengthy investigation and Dan just provided the pertinent information, like he said in, I think, a previous e-mail, they don't provide the whole entire investigation, but they'll provide a summary of the investigation. So -- and I believe too he had even -- he had asked me, is this, you know, is this what you want to see and we were comfortable with, yeah, this was the important part. We didn't need, you know, all the extra attachments.

Q. But you do agree that ultimately this batch was released -- yes, it's the right term; ultimately you did release this batch?

A. We released it and then, yes, we released it and then it was recalled.
Q. Were you part of the recall at all?
A. Define part of.
Q. Well, you talked about your duty was reviewing COC's and COA's and quality agreements; did your daily functions change once the recall happened?
A. No. My only participation would have been if a batch record was needed.
Q. Do you have a memory of batch records being requested because of the recall?
A. I don't.
Q. I'm going to mark Mylan 12.

* * *

(Whereupon, Deposition Exhibit M-12 marked for purposes of identification.)

* * *

BY MR. MILLER:
Q. It's Actavis document 00514193 and you can see that, do you agree that it's an e-mail from you to Dan Bitler?
A. Yes.
Q. Do you recall this particular e-mail or the conversation?

A. Yes.
Q. We have -- do you agree we had the January of 2007 discussing getting the quality agreement from Mylan and in May of 2007, I believe it was a request to legal from you and now in November of -- 27, 2007, do you agree that you're requesting that Dan review and sign the same document that was in question in the other e-mails?
A. Yes.
Q. That was a convoluted question.
A. But I followed it.
Q. I was holding on. Was it an issue with you in your duties with quality agreements that it was taking so long for this document to get signed and in the file?
A. Was it an issue?
Q. Yeah, was it an issue or a concern, a problem?
A. It was a concern in that that was one of my tasks to check off, it's part of my job duties is to implement and institute technical agreements and put them in place.
Q. Well, did you feel any pressure that a quality agreement with Actavis needed to be in

place because of regulatory issues at Actavis?
A. No, absolutely not.
Q. Down at the bottom, it has the about -- let's see, October 17 there is an e-mail going from you to Dan roughly six weeks prior where you say: Dan, see attached agreement. Once you review, please provide any comments if you'd like revisions or if not I can have a duplicate original prepared for signature. Do you recall ever receiving a reply from Dan Bitler in which he requested changes?
A. No.
Q. Did Dan Bitler ever exchange e-mails with you regarding the quality agreement at all; did he reply?
A. Yes.
Q. And what type of replies were you getting when you were requesting this document to be signed?
A. Usually -- if I recall just that he was extremely busy and he just -- he knows he needs to review, he just hasn't had time to get to it yet, that type of reply.
Q. If you turn the page to Actavis 00514194 and look at the bottom, I guess would be

the first e-mail, it's from you to Dan, where it says: Good morning, Dan, can you please send the documents for Digitek 70673A1. Thank you very much. My question is, did typically on a lot, if you knew that a lot needed a batch record, you, every time would e-mail him that you needed it or did it automatically come?

A. No, not every time. There were times sometimes when I didn't have the documentation before the batch was received down at the distribution center. So I would request it.

Q. Do you recall any particular issues with that lot?

A. No.

Q. It's not stapled but I'm going to mark this as M-13.

* * *

(Whereupon, Deposition Exhibit M-13 marked for purposes of identification.)

* * *

THE WITNESS: When you run out of stickers, are we done?

MR. MILLER: I have 200 of them over there.

THE WITNESS: Darn it.

MS. MCDONOUGH: At some point we might want to break for lunch when it makes sense.

MR. MILLER: This is a good time for everybody. I'm going to jump into this for a while. So it might be a good time. Let's go ahead and do it.

MS. MCDONOUGH: Okay; that sounds good.

VIDEOGRAPHER: The time is 1:48; we're going off the record.

* * *

(Lunch break taken)

* * *

VIDEOGRAPHER: The time is 2:37; we're back on the record. This is the beginning of disc two.

BY MR. MILLER:

Q. Well, right prior to lunch, ma'am, I handed you what I've marked as exhibit M-13. I was wondering if you could take a look at it and tell me if you've seen that document before?

A. Yes, I have.

Q. Okay.

And you -- this is Actavis 00514195,

and would you agree with me that this is the quality agreement that you were requesting Dan Bitler to sign on behalf of Actavis?

A. This is a draft version.

Q. And if we go to what's marked as page one, the third page of exhibit Actavis 0514197, it starts out quality agreement at the top, was this quality agreement as made and entered into as of this third day of August 2007, the effective date, does that date jog your mind as far as if this is the final draft or a rough draft?

A. This is a -- it's a draft version. In other words, the date that's at the top would be the date that this was originally first written and I say it's a draft because of the very last page. There's information that needs to be completed there.

Q. All right.

And that was reflected in the e-mail; would you agree that you're saying this to Dan Bitler in order to complete with the Actavis information that you were asking for?

A. Yes.

Q. Okay.

And you agree this quality agreement

was to be a quality agreement that was going -- directed to the product Digitek at Actavis?

A. Yes.

Q. Okay.

If you go to that same page where we saw the date, page one, and it says a paragraph, 1.0 quality requirements and the second paragraph under that title, it says: This agreement defines the operating procedures to be followed when products are manufactured by Actavis for Mylan Bertek to ensure compliance with CGMP and other regulatory requirements. My question is, what agreement, if any, would have controlled what's defined in that paragraph prior to this quality agreement being in place?

A. Whatever would have been stated in the supply agreement and just the company itself at Actavis's own internal procedures and systems.

Q. Okay.

So a quality agreement really isn't put in place to replace the production agreement, it's to add to --

A. The supply agreement?

Q. Supply agreement; I'm sorry. Yes.

A. Oh, absolutely, it's not to replace

it at all.
Q. Did you write this draft?
A. Yes, in conjunction with legal.
Q. All right.
Was there a boilerplate or template of sorts that you would have altered to conform to Actavis or would you have started from scratch to generate this?
A. A template.
Q. Okay.
And for Actavis in particular, other than going through and changing the name of the companies that you're dealing with; was there any substantial changes to the document that you recall from the template to this?
A. Not that I recall, just the appendices would be specific to the site.
Q. And is there an SOP at Mylan that defines what language is inside the quality agreement?
A. There is an SOP, a technical agreement, I'm not sure if it defines what's to be in the technical agreement. The SOP is about the process, creating it, generating it.
Q. Who's the holder of that SOP as far

as which department at Mylan?
A. Well, the SOP that exists now, I drafted it for -- because that's what I do, to create technical agreements, quality agreements right now.
Q. Did you -- do you recall when you wrote that SOP?
A. Actually I think Chuck Koon wrote the latest one. There was a previous version, I believe, that I wrote and I think the existing SOP right now Chuck Koon wrote and I don't recall when I originally wrote it.
Q. Was it revisions to a previous SOP or did you start from scratch?
A. Scratch; started from scratch.
Q. Because the SOP prior to that SOP was terminated or because there was no SOP in place?
A. None existed.
Q. And what was the title of the SOP?
A. Something along the lines of creation of quality agreements or technical agreements.
Q. And do you recall exactly when that was -- that SOP was first created?
A. I don't, no.
Q. But you believe it was not in place

when this was in circulation in August of 2007? Excuse me.

A. The SOP?

Q. No, the SOP, right, the SOP of that creating quality agreements?

A. I don't know.

Q. If you go to page, numbered page two, I believe the fourth page of the document, 0514198, and there at the top it says manufacture, 3.1 premises and 3.1.1, it says: All products supplied to Mylan Bertek shall be manufactured at Actavis's Lincolnton, North Carolina plant. Do you believe that to be a typo or something that needs to be changed?

A. Yes, it would be.

Q. Okay.

And do you know where Actavis produced Digitek back when it was being --

A. Totowa.

Q. So back when you were drafting this you would have replaced that information with Totowa?

A. Yes.

Q. Paragraph 3.12, the next paragraph down, it says: The premises and equipment used for

manufacture must be in compliance with CGMP's, current regulatory requirements, and in accordance with the documentation approved by FDA. Is that something that you would have put in this document or as part of the template?

A. That's standard language.

Q. Does the SOP regarding creating QA's that you worked on in any way address how that information is going to be passed from the third-party manufacturer, Actavis in this case, to Mylan?

A. I don't understand your question.

Q. As a drafter of the QA, how was it planned or perceived that Mylan would keep up with the fact that the premises and equipment were going to be within compliance of GMP's?

A. Well, the sites are periodically audited.

There is an auditing section within the quality agreement that states that Mylan will be allowed into the facility to audit.

Q. And as the QA of third-party production plants, is it your statement that through audits Mylan would determine if Actavis was in compliance with GMP's?

A. That would be one of the ways.
Q. Is one of the ways also to request FDA inspections such as a 483?
A. We don't -- we can't request inspections from the FDA. The FDA inspects on their own.
Q. I'm sorry, request a copy of the report that results in a 483 inspection, the 483 report.
A. Yes, that's also covered in here.
Q. Would it have been -- I may have asked this already, I'm not sure. Would it have been you as QA manager for third-party production companies, the one that would have requested 483's or someone else in the quality department at Mylan?
A. I could have. It could be anyone within quality could request them.
Q. And again, I think I might have asked this but at no time did you -- you did not request any copies of 483's from Actavis while you were the QA of third-party production facilities?
A. No.
Q. Throughout the document, I think part

of what I just read, the term Mylan Bertek is used. Am I correct in saying that Mylan didn't distribute any Digitek tablets under the Bertek label after 2005?

A. I don't know.

Q. What's the significance of the term Mylan Bertek when it's used together?

A. Legal would have used that name when they reviewed this. Legal puts that in, usually it's however the supply agreement is written, whatever parties, however that language is used for the parties in the supply agreement, that's the language that's used for the technical agreement.

Q. Would this quality agreement carry over and cover tablets that were distributed to UDL as well?

A. No, this agreement is specific to the two parties on the front. And the first paragraph, the preamble, it says Chestnut Ridge, Morgantown, West Virginia.

Q. Uh-huh. I'm sorry. What's the --

A. That --

Q. -- significance?

A. That's who this agreement is with. It's between Actavis, Totowa and Mylan Bertek with Chestnut Ridge, Morgantown, which is the site here in Morgantown.

Q. I got you.

I'm going to mark Exhibit 14, M-14. Take a look at that e-mail and this is document Mylan 0034729.

* * *

(Whereupon, Deposition Exhibit M-14 marked for purposes of identification.)

* * *

BY MR. MILLER:

Q. Take a look at it and let me know if you recall the e-mail or the topic of.

A. Yes.

Q. And do you recall the e-mail because it's specific to out of specification assays or why is it that you recall this particular e-mail?

A. Let me correct, I don't recall this particular e-mail. I recall this e-mail because there were several e-mails of this type that went back and forth between UDL and myself on this subject.

Q. But it's from you to Connie Hatcher;

who is Connie Hatcher?
A. According to this, she's the senior sales administrator at Mylan.
Q. At Mylan? Why is it that someone from Mylan is requesting assays that comport -- that are within specifications of UDL -- wait, I lost track of that question.
Why would someone from Mylan be requesting assay information on a lot for UDL?
A. Because Connie works -- apparently part of her job function is releasing, not releasing, but -- I don't know the term they use, she gets the batches for UDL, distributes the batches for UDL, takes the purchase orders, whatever is involved.
Q. Is Connie still at Mylan?
A. I don't know.
Q. How many employees does Mylan have here in Morgantown?
A. In Morgantown, I'd say 900, I believe.
Q. In early 2008, do you recall conversations with Dan Bitler or anyone at Actavis about the fact that they were moving their plant?

A. Yes.
Q. How did that, if it did in any way, affect your job clearing or releasing lots through batch records?
A. Only in the sense that I needed to know if the new facility was validated and if any of the product, any of the batches we were receiving, what site were they coming from, the old or the new.
Q. And what do you mean by validated?
A. Well, all the equipment, the building itself, the whole processes that are done at every site needs to be validated and you have to prove that to the -- a quick summary is just that you have to prove to the FDA that you are manufacturing everything within tolerances and specifications.
Q. And would you request verification from Actavis that that validation took place?
A. I believe we did. I don't recall if I personally did, but I believe it was requested from Actavis.
Q. I'm going to mark as M-15 --
MS. MCDONOUGH: It's 16 now.
MR. MILLER: 15 (fifteen).

COURT REPORTER: 15 (fifteen).

MR. MILLER: Gosh, normally I'm the one that's always wrong on that.

MS. MCDONOUGH: I apologize.

* * *

(Whereupon, Deposition Exhibit M-15 marked for purposes of identification.)

* * *

BY MR. MILLER:

Q. Let me know when you've had a chance to take a look at that.

A. Okay.

Q. Do you recall the topic?

A. Yes.

Q. Do you recall this particular e-mail?

A. Vaguely, yes.

Q. Who was -- let's see, you've got the -- I'm not going to read it into the record, but there's the e-mail from Dan Bitler to you and you agree that it's his write up on how things were going as far as the Digitek move from one facility to the other; is that correct?

A. Yes.

Q. All right.

And then if we turn to the first page, at the very bottom, it's a paragraph that begins with Chuck and it ends with Suzy and it says: Chuck, obviously I'm asking to see all validation batch records and was not sure if you want to visit/audit the new site prior to release of the product for distribution. FYI, I asked why we weren't notified earlier and the response was we're so busy, I forgot about it until now. Suzy.

Is that an e-mail from you to Chuck?

A. Yes, at the top it says it's to Wayne Talton and Chuck Koon.

Q. Okay.

And who is Wayne Talton?

A. Wayne is regulatory affairs.

Q. And this -- am I paraphrasing this correctly that you're letting Chuck Koon, who you report to, know that you're looking to see validation batch records that regard to the move?

A. Yes.

Q. And is that validation batch records, is that what you were discussing earlier when you say that there had to be validation from the move?

A. Right.
Q. And it would come to you in the form just like a batch record that you received on other batches, but it will be a batch record dedicated to the move itself?
A. It can and typically there is a summary report, the whole validation summary report.
Q. Is it a summary report about -- by way of example because I don't know, would it be the first couple lots that they tested at the new facility and they would do extra tests because the facility is new and it would just be that a batch record that you're used to seeing with additional paperwork because of the move? I'm probably wrong but if you could explain to me what you would expect to see in a validation batch record.
A. Actually, you're pretty close. It's a validation of the first, typically it's usually the first three lots that are manufactured and packaged. And you would see a normal batch record, everything is done normally, there's not extra tests that are performed. It's just three consecutive batches, typically.

Q. Did you receive that on the first three consecutive batches after Actavis moved from Little Falls to Totowa?
A. I really can't remember if I did or not.
Q. Does the fact that you stated FYI, I asked why we weren't notified earlier and the response was we were so busy, I forgot about it until now; does that jog your memory as to not being given information that you were requesting at the time?
A. I would say that it -- I probably was given the information. We had a very cooperative and I had a very cooperative relationship with Dan. So usually anything I asked for, he provided.
Q. Do you have a memory of getting validation batch records on any lot after the move took place?
A. I don't, and we might not have specifically got batch records. We might have got the actual validation report, which summarizes all of the batches.
Q. And it's that validation report, is that something that's also sent to the FDA or is

it just internally generated?
A. It's internally generated.
Q. But it would be titled validation batch record?
A. Each company titles it differently.
Q. I guess my question is though, you don't have any specific memory as we sit here right now of receiving a validation batch record from Actavis after their move to Totowa?
A. No.
Q. And then up at the very top, Wayne replies saying: Suzy, it looks like that had -- wait a minute, if I can read that, it looks like: that have had good interaction with FDA on this matter, however, I don't see anywhere in his e-mail where he talks about the regulatory strategy, and I'll stop there.
When you received this e-mail, did you understand that to going to your question about not receiving validation batch records? Is that how you read it?
A. No.
Q. How do you read that sentence?
A. What Wayne is inferring has to do with -- Wayne's not involved with validation at

all. He's involved with the regulatory side. So the submissions of the documentation -- there's -- I can't speak for regulatory but there's forms and reports that have to be written and submitted to the FDA.

Q. That are a part of the validation of the new facility?

MS. MCDONOUGH: If you know.

THE WITNESS: Yeah, I might -- I don't know.

BY MR. MILLER:

Q. It goes on to say: Is FDA allowing them to switch the new site via an annual report notification, parenthetically, since they are using the same establishment number, end of parenthetical, or are they submitting a CBE-30 supplement; are you familiar with that language?

A. Uh-huh.

Q. Now am I paraphrasing it correctly that he's assuming that if you keep the same manufacturing number and you go from one plant to the other, that you don't need a validation report?

A. He's not saying validation report. It's a -- it's whatever regula -- whatever

documentation that regulatory needs.
Q. Do you recall having any more exchanges of e-mail on the topic beyond this?
A. I don't recall.
Q. During the time of this e-mail, February 15 of 2008, as the quality assurance director for third-party production facilities, is it your job to ensure that the validation batch records are received by Mylan?
A. If it's -- if it would be something that we would like to have, it would be my job to request them.
Q. Is it something that the company would like to have?
A. I can't answer for the company.
Q. Is it something that you would like to have had as the QA of third-party production --
A. It would have been nice to have or a validation summary.
Q. One or the other?
A. Something -- yes, something to provide evidence that, yes, the site has been validated and it's okay to have production.
Q. Would it affect your

duties as quality assurance director of third-party production if they moved from one place to the next and didn't produce a validation batch record?

A. Not so much if they didn't produce, if they didn't -- what's more critical is whether they did the validation or didn't do the validation. That's what's critical.

Q. Why would it be critical if they didn't do the validation?

A. Because you can't really run any product in a site on equipment that hasn't been validated.

Q. Is that a safety -- safety issue?

A. It's an FDA requirement.

Q. Is it an FDA requirement because it's a safety issue?

MS. MCDONOUGH: If you know.

THE WITNESS: I don't know what the FDA's reasoning is behind it, whether it's safety or not safety.

BY MR. MILLER:

Q. I'm going to mark M-16.

* * *

(Whereupon, Deposition Exhibit M-16

marked for purposes of identification.)

* * *

BY MR. MILLER:

Q. And it's Mylan document 0025907; do you recall seeing this document?

A. This one in particular, no.

Q. Am I accurate in saying that this is what you would receive as a batch record much like the one we previously saw except for here we don't see your cover letter and we don't see the barcodes. So it's what you would get before you put your final stamp of approval on it?

A. Yes.

Q. All right.

And then this is for batch number 80202A1; is that correct?

A. Yes.

Q. And it appears that there is a sticky that says hold OOS weights; do you agree with that?

A. Yes.

Q. Is that your handwriting?

A. It appears to be. It looks like it.

Q. Does it -- what do you mean by hold?

A. Well, I don't know the background of

this document or where it came from and what context it was pulled. So I'm -- you know, hold would mean -- I'm not sure what the interpretation was here.

Q. Okay.

What do you mean by -- what's OOS?

A. Out of Specification.

Q. And is that weights underneath that?

A. Yes.

Q. And what, if you know, what weights would that refer to?

A. There's none that are on the C of A, so I don't know which weights those are.

Q. And in fact, there's never any weights on the C of A, right?

A. Right.

Q. So would that be something that would -- obviously you would have to gather that information from a source other than the batch record itself?

A. Right. Right.

Q. Was that -- is that typically how it would happen, if some issue was with a batch, if it ever happened before, someone would either call you or e-mail you and say put the brakes on

that one, we have -- there's something going on?
A. I could receive a phone call like that.
Q. Do you have a memory of it happening more than this one time?
A. No.
Q. But you don't have a specific memory of it happening here?
A. No, I don't.
Q. And if -- what would be your procedure as a QA of third-party production plants once you were informed that something needed to be held because of weights, then is there additional paperwork that you would need to receive before you would release this batch?
A. Additional paperwork that I -- I need to understand your question better. If I would receive --
Q. How do you go about verifying that it's now within weights? If it was out of specification for weight, what do you do to make sure it's in specification for weight in order to release it; what's the next step? If it sits here on the desk as a hold --
A. Right.

Q. -- what's got to happen for it to no longer be on hold?
A. Well, if there truly was an issue with out of specification weights; I would need an investigation that would explain the corrective action and show the preventative action and what happened.
Q. And you don't have a memory of getting an investigation on this particular lot?
A. I -- no, I don't. I need more information.
Q. I'm going to mark M-17.

* * *

(Whereupon, Deposition Exhibit M-17 marked for purposes of identification.)

* * *

BY MR. MILLER:
Q. Do you agree this is an e-mail from you to Janet Kinsley and subject line, Digitek batches on hold? And that top part from you, if it says don't inspect the -202 batch. Would it be common for you to truncate the first portion of the lot number and just use the 202?
A. It's not significant. Yes, I could have.

Q. I'm not saying it's significant. Would you agree with me that that -202 is the same lot that we're looking at on the previous --

A. Yes.

Q. And it goes on to say: They indicated that this one is a problem child and that the other two should be okay, ran on a different press or something, so felt strongly they would be coming off of hold. Regards, Suzy Wolfe.

Now that I've read that; does it jog your memory on receiving information regarding the press at Actavis?

A. I remember they had an issue and I remember I received a phone call or an e-mail about these batches or batches they were having an issue with. I don't recall what happened after this, what subsequent information came after this.

Q. Do you remember any other issues with presses at Actavis?

A. No.

Q. Do you know what you meant when you typed in the word, when they ran off of a different press or something; what does a press mean to you?

A. A compressing, a press is something that compresses the tablets.

Q. Okay.

I'm really rifling through them now.

THE WITNESS: It's okay, keep going.

MS. DOWNIE: You only have a few stickers left.

MR. MILLER: Choose your exhibits wisely.

BY MR. MILLER:

Q. I'm going to hand you Mylan 18, and it is Mylan document 0032805 and it's from you, unfortunately we don't know who it's to. When you're done reading it, let me know.

* * *

(Whereupon, Deposition Exhibit M-18 marked for purposes of identification.)

* * *

THE WITNESS: Okay.

BY MR. MILLER:

Q. This April 10 e-mail in which you generated, okay, when you indicate all, all the cc's are folks within Mylan; is that correct?

A. Yes.

Q. Was there a group e-mail address where you could send -- I forget the Microsoft term, where you group a bunch of contacts together and you can just use that one identifying e-mail and send it to numerous folks; did you have that at Mylan?

A. For these?

Q. Yes.

A. Did we have the ability to do it? Or --

Q. Did you use it? I mean did you use it for this topic or any topic?

A. No.

Q. But you discussed information, the reference batch was originally packaged as 70924A1 and it talks about the double thickness. Would you have gathered this information from the report that was given to you regarding the double thick batch or do you have a memory of gathering this information from someone at Actavis?

A. I would have -- I would have gotten this from Actavis. Well, it could also be part of the documentation too; here it says the batch documents were reissued. So I would have had batch documentation in hand.

Q. Would you consider yourself the primary point of contact with Actavis during this, I'm going to call it the build up to the recall?

A. I was initially and then it escalated above me.

Q. And what do you mean by escalated above you?

A. Once we received -- I received a phone call that the FDA was on-site and the batch was being recalled. There were several batches, I think initially maybe that were listed as part of the recall. Then it went on to my upper management.

Q. Was it your understanding that the FDA was on-site at Actavis because of this -- because of the issue, because of the double thickness --

MR. TABER: Objection.

MR. MILLER: -- issue?

THE WITNESS: I didn't know specifically why the FDA was there.

BY MR. MILLER:

Q. Did you ever learn why the FDA was there?

A. After the fact?
Q. After the fact.
A. I heard a reason why they could have been there.
Q. What was the reason you heard why they could have been there?
A. Issues with following up on observations, that the FDA had issued observations and they weren't getting the follow-up that they wanted.
Q. Did you ever become aware that all products at Actavis, production of all products at Actavis was halted?
MR. TABER: Objection, that's not current.
MR. MILLER: Not current?
MR. TABER: You said Actavis. You mean the one plant.
MR. MILLER: I'll try that again.
MR. TABER: I didn't mean to interrupt.
MR. MILLER: No, that's okay.
BY MR. MILLER:
Q. Did it ever come to your attention

that all products at Actavis Totowa, the production of all products at Actavis Totowa was ceased following the inspection by the FDA?

A. Yes.

Q. And did you ever learn why?

A. The FDA had issued that mandate.

Q. Did you as the QA director of third-party manufacturing plants ever investigate if --

A. You just promoted me, but that's okay.

Q. Okay.

As QA of third-party production facilities at Mylan, did you ever do any research, investigation to determine if the Digitek recall was separate and apart from the reasons why FDA was on-site at Totowa?

A. No, I had no involvement.

Q. What time is it getting to be?

MS. MCDONOUGH: 3:20 I have.

BY MR. MILLER:

Q. Did you have any involvement at all in the recall letter for Digitek?

A. Recall letter from?

Q. From Mylan.

A. No.
Q. The recall letter for Actavis?
A. No.
Q. Did you receive a recall letter from Actavis?
A. No.
Q. Have you ever seen any recall letters associated with Digitek recall?
A. I'm sure I have since that time.
Q. It would have been something you were researching on your own or came across your desk as part of your duties and functions as QA of third-party production?
A. Not necessarily research on my own, but since I was involved with the site early on, I'm sure it was shared with me at some point.
Q. Did Actavis generate a recall team?
A. I don't know.
Q. You're not Ann Wolfe, we established that.
A. She's blonde.
Q. Do SOP's ever get violated at Mylan? I mean if Mylan has an SOP and it's their own internal SOP and it's not followed, is there any type of -- any type of repercussion or is there

any follow-up on that?

MS. MCDONOUGH: Well, objection, it's vague. Can you be a little more specific, what kind of SOP, what kind of violation, something like that?

MR. MILLER: Strike that question.

BY MR. MILLER:

Q. I'm going to hand you what is marked, will be M-19. Take a look at that, ma'am. I'd greatly appreciate it.

* * *

(Whereupon, Deposition Exhibit M-19 marked for purposes of identification.)

* * *

BY MR. MILLER:

Q. I'm assuming there's more to his name than what's typed here, but who is William Brochu?

A. He is the -- he's uhm, I want to say, I don't know his title, but he's like the plant manager, he's a quality director, vice president; he's head of quality, whatever title that is of Vermont MTI, it's called site, Mylan Technologies.

Q. And it starts out an e-mail that's -- you were copied on, an e-mail that was neither sent or received by you, but it was forwarded to you and it's: Ron, it's written by Bill, attached is a complaint letter related to Mylan's recent Digitek recall. It's not clear to me why the complainant chose to send it to us. So were you informed that a Digitek complaint went straight to his office?

A. Was I informed?

Q. Is that why this e-mail is being sent to you?

A. I'm not really sure why I was copied on this because the complaints go to our PSRN group, product safety. I was copied on it.

Q. Then you forwarded it on to -- at the very top, it starts, it says: Chuck, the attachment is a letter from a physician/patient who is disgruntled about how the Digitek recall was handled, parenthetically 8 pages worth, exclamation mark. I have left a message with Ron asking him how they are handling this complaint. Will let you know, Suzy. Now are you asking him how they're going to handle this particular complaint or are you asking him how are they

going to handle complaints? If that question makes sense to you.

A. Uh-huh. Well, it appears to be specifically this complaint, how they were handling this complaint.

Q. Do you recall why that complaint had significance?

A. Only because it crossed my desk or I was copied on it.

Q. Well, wouldn't the handling if it was like any other complaint, wouldn't you have sent it to the facility that standard -- was typically the recipient of complaints?

A. Well, that's who Ron is I'm referencing here.

Q. Okay.

A. Ron is the one that handles the complaints. I sent this to Chuck just as an FYI because I knew he was involved with the recall.

Q. Well, if there's a system in place where the complaints are absorbed into a software or the system that you had described, why wouldn't it be that you would just let him know here's the complaint? I'm curious as to why you would say I've left a message with Ron asking him

how they're handling this complaint?
A. Well, because this complaint is not about -- it's not about the product itself. It's about the system itself, the process, the Digitek recall itself.
Q. But do you agree that you had no action in this type of complaint or any type of complaint, that the complaint would go through your --

* * *

(Brief interruption)

* * *

THE WITNESS: Sounds like my ring. Repeat that question, please.
BY MR. MILLER:
Q. The question is whether it was a complaint dealing with the recall or a complaint dealing with an adverse event or whatever, you didn't handle any of those complaints, right?
A. Right.
Q. I'm just curious why you were looking for information as to how this particular complaint is going to be handled; what difference does it make to you how it's handled?
A. It doesn't really for me. I was just

being a good employee because I knew Chuck would ask. So I was getting information for him.

Q. When you say it is a letter from a physician/patient because you don't know or because it's both, can you recall?

A. I don't know. I'd have to see the letter.

Q. Did it happen often that complaints came to you and you had to reroute them or is this something that occurred rarely?

A. No, I would rarely receive them.

MS. MCDONOUGH: Just for clarification, it does look like on page two it went to Ron, the person who does normally handle these complaints, but then it was just cc'd to several other people also. So I don't know if that's helpful, but --

MR. MILLER: Right, no, I agree. Okay. Do you have questions?

MR. FRANKOVITCH: I have a few.

MR. MILLER: I'm probably going to have a couple cleanup, but I'll let Carl jump in and --

MS. MCDONOUGH: Sure.

MR. MILLER: Can you do it from there, so we can just stay here?

MR. FRANKOVITCH: Sure.

* * *

E X A M I N A T I O N

BY MR. FRANKOVITCH:

Q. Ms. Wolfe, my name is Carl Frankovitch and I'm going to ask you a few questions. They'll probably not make as much sense as Pete's did, but they're on my mind so I can get it straight.

The hierarchy at least from Ms. Latzo, is that how you pronounce it?

A. Uh-huh.

Q. Latzo down was -- Mike Adams was below her?

A. Yes.

Q. Is that correct?

A. Yes.

Q. And then Mr. Koon would report to Mr. Adams?

A. Yes.

Q. And you would report to Mr. Koon?

A. Yes.

Q. And Mr. Koon, as I understood your

testimony, had two departments reporting to him, yours; is that correct?
A. Right.
Q. Which was quality assurance manager, outsourced products?
A. Right.
Q. And that was you individually and occasionally a helper?
A. Yes.
Q. And then there was the auditing group and how many were in the auditing group; do you know?
A. Four.
Q. Okay.
So he had essentially five people reporting to him?
A. Yes.
Q. Where were you -- these two groups located; were you all out here on Chestnut Ridge?
A. Yes.
Q. And Mr. Koon was out there too; I take it?
A. Yes.
Q. Were you near each other, same floor --

A. Uh-huh.
Q. -- same complex of offices?
A. Yes.
Q. The way you describe your function was that you would get a Certificate of Compliance and a Certificate of Analysis and that you would determine whether they -- the Certificate of Compliance said that they were in compliance --
A. Uh-huh.
Q. -- and their Certificate of Analysis was the analysis was within your parameters?
A. Right.
Q. And that's all you did?
A. Yes.
Q. That was your whole job?
MS. MCDONOUGH: Well, objection, with regard to a specific thing or --
MR. FRANKOVITCH: To your routine work?
THE WITNESS: For Digitek it was.
MR. FRANKOVITCH: Right, for Digitek.
THE WITNESS: For Digitek and

for releasing a batch for Digitek, yes.
BY MR. FRANKOVITCH:
Q. Okay.
And what other types of things did you do besides -- there was eight products as I understand it?
A. Right.
Q. Did you do something different for the other products?
A. Some of those products, entire batch records were received, so I would have to review an entire batch record, batch record being about this thick (indicating), which is all the manufacturing, all the production, reviewing any of the investigations, if there are investigations involved with that and writing, drafting and creating quality agreements and technical agreements.
Q. Okay.
But as it related to Digitek, you didn't have to do anything else. You didn't rely on their Dig -- on their batch records, you relied on their Certificate of Compliance and their Certificate of Analysis to approve them?
A. Yes.

Q. While you were there, you said it was sort of off the record discussions or locker room discussions or something about problems that might be out in the field or out in these outsourced facilities; is that correct?
A. Yes.
Q. The -- is it your recollection that nobody ever mentioned to you that there was a problem down at Actavis as it related to Digitek?
A. At some point in time I knew. I don't recall now when that was, at what point.
Q. Were you curious as to whether 483's had been issued?
A. I don't know if I understand what you're saying.
Q. Well, I think you said that you never saw a 483 relating to Actavis inspections and Digitek?
A. Correct.
Q. Did -- and you'd never asked to see if there were any?
A. Right.
Q. When you heard reports that there was some friction with the inspection --

A. Uh-huh.
Q. -- in Totowa, did you ask anybody were there any 483's issued?
A. No, because I knew there were others in quality that were involved.
Q. But you in particular was the individual who would each time you approved a batch would say that it was produced with good manufacturing processes?
A. Right.
Q. Did you ever try to confirm that?
A. It was not really part of my responsibility to actually confirm that. Part of the auditing, when we send auditing teams out, that part of their function is to do that.
Q. Were -- when you found out that the, and I think you said you did see the warning letter and the 483 subsequently?
A. Uh-huh.
Q. Did you ever go to somebody and say why didn't you tell me that there were issues there?
A. It wouldn't have mattered if I had.
Q. Well, did it disturb you that for a couple of years you were verifying that they were

meeting good manufacturing practices when the government was issuing reports that they weren't?

MR. TABER: Objection.

THE WITNESS: Yeah, I don't know that the government is -- was issuing reports that they weren't. The government issues observations like I stated earlier and 483's at lots of companies.

BY MR. FRANKOVITCH:

Q. Right, but you subsequently saw the correspondence, the 483's and the warning letter --

A. Right.

Q. -- that challenged whether they were meeting good manufacturing processes and whether they were shipping adulterated products.

MR. TABER: Objection as to the question. It's broad.

MS. MCDONOUGH: Same objection and it is vague.

BY MR. FRANKOVITCH:

Q. Well, did you -- at some point you saw the warning letters --

A. Uh-huh.

Q. -- that indicated that there was at least the possibility of adulterated products being shipped from the plant?

MR. TABER: Objection.

THE WITNESS: I never saw the term adulterated products.

BY MR. FRANKOVITCH:

Q. Well, and it may not; it may not be that term. It may not say adulterated products. I stand corrected. It did say that there was significant deficiencies found and I'm not paraphrasing, but I'm -- well, I'll read it.

Significant deficiencies were found in the operation of the firm's quality control unit and as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess.

MR. TABER: Objection, over broad.

MR. FRANKOVITCH: Do you remember seeing that?

THE WITNESS: Yes.

BY MR. FRANKOVITCH:

Q. Did -- and that letter was issued in February of '07, but you don't think you saw it until sometime after the recall?
A. I believe so.
Q. Okay.
When you saw it, did you ever confront anybody else that had it in the auditing department and then say why didn't you pass this on?
A. No.
MS. MCDONOUGH: Objection. I don't know that there's a foundation that someone there had that letter at that time at Mylan. If you can answer, go ahead.
THE WITNESS: I guess my point is it doesn't really -- it didn't really matter because those that needed to be aware were aware.
BY MR. FRANKOVITCH:
Q. The -- you think they were aware of this?
A. I'm sure, yeah, I'm just -- I'm guessing, so I should say I don't know.
Q. It's something they should know though?

MS. MCDONOUGH: Well, objection, that calls for speculation and has no foundation, should know why, for what reasons, were they apprised of it. I mean that's open-ended and lacks foundation.

BY MR. FRANKOVITCH:

Q. Did you ever after you learned of it have a discussion with anybody, either Mr. Koon or Mr. Adams or any of your -- the other four people in the auditing group to say were they aware of these issues?

A. I don't recall any specific conversations.

Q. Was the -- when you were confirming that these products were made with good manufacturing practices, you were relying strictly on what Actavis had related to you; is that right?

A. Yes.

Q. The -- and this is just informational I guess, what's the abbreviations in the e-mails, GSO and MGW?

A. MGW is Morgantown.

Q. Okay.

A. GSO, it might be Greensboro. I think

it's Greensboro.
Q. Okay.
The -- as I understood your testimony, so we don't have to go back through it, you verify or confirm that there was a COC and a COA and the product would be, what, then shipped to the distribution center or would it be there and you would receive these?
A. The latter. It would --
Q. The latter -- it would be there, you would get the COC and the COA?
A. Right.
Q. Did you -- were you involved in any way with where it went after that?
A. No.
Q. Do you know where it went after that?
A. No.
Q. Could you determine where it went after that?
A. Could I determine?
Q. Right.
A. Today, could I --
Q. Well, at the time at least?
A. I don't know that I could have.
Q. Who would be the person that would

know that?
A. Someone in our sales and distribution group.
Q. That's -- you wouldn't have any -- you were designated as somebody that may know, have that information as to distribution and sale of Digitek to Wal-Mart?
A. No, once I release the product, I have no idea where it goes.
Q. Okay.
And you're not involved in the sales of that to Wal-Mart or distribution to Wal-Mart; you don't have anything to do with that?
A. No.
Q. Okay.
Who would know that; do you know the individuals?
A. Now I don't know. Again, we've had, you know, management changes. I'm not sure. At that point in time it would have been Ann Wolfe would know. She may still, I'm not sure if she still is in that same job function.
Q. And where is she located, here in Morgantown --

A. Yes.
Q. -- or Greensboro? Okay. Is there anybody else?
A. I would only be guessing and I don't know.
Q. But she would be the most knowledgeable that you know?
A. She would be knowledgeable. I don't know if she's the most knowledgeable.
Q. To be clear in my mind, the relationship of UDL and Mylan is what?
A. UDL is a re-packager for Mylan. They are an affiliate though, a sister company, whatever term you want to use for Mylan.
Q. Okay.
They're essentially controlled by Mylan; the parent?
A. Yes.
Q. And then Mylan Bertek functions how?
A. That I don't know. I don't know. Bertek used to be years ago its own entity. It merged and for tax reasons the name still exists.
Q. So there's a Mylan Bertek and there is a Mylan?
A. That's all I know.

Q. Okay.
Is the UDL -- all they do is repackage?
A. I think so.
Q. Okay.
Why would their parameters we talked about, why would they be different than Mylan's parameters?
MS. MCDONOUGH: If you know, don't guess.
MR. FRANKOVITCH: If you know.
THE WITNESS: Yeah, I don't know.
BY MR. FRANKOVITCH:
Q. Is the product sold to a different customer?
A. Again, I don't know.
Q. Do you know who establishes those -- those -- the tighter parameters for UDL?
A. No.
Q. Does UDL -- when a product doesn't meet UDL's parameters, do you follow me?
A. Uh-huh.
Q. What happens to it?

A. It's not shipped to UDL.
Q. Okay.
I thought everything went to UDL?
A. No, everything goes to Greensboro.
Q. And that's the --
A. That's the distribution --
Q. -- distribution center?
A. Right.
Q. And UDL and there's another shipment then to UDL's plant?
A. Yeah, a portion of an existing batch, yes.
Q. Where are they located, UDL's plant?
A. Rockford, Illinois.
Q. Okay.
And then what happens to the stuff that doesn't go to UDL?
A. That's released to whomever, other customers.
Q. Is it a classic customer that makes the distinction between UDL and the other customers?
A. UDL repackages in blisters, so it's whatever a customer requires in blister pack. Actavis doesn't have the ability to -- they ship

it to us in bottles --
Q. Okay.
A. -- bottles, so UDL repackages in blisters. So if there's a particular customer that would require blisters --
Q. The -- I believe it's Exhibit 16, there was a sticker on it that says hold OSS -- OOS, out of spec?
A. Yes.
Q. How would you get that information? Who would tell you that it's out of spec?
A. Dan, Actavis would have told me.
Q. But I mean this -- these documents would have shown that it's in conformance and the analysis is correct.
A. Weights aren't on here. Weights are an in process check that are done during the manufacturing of the product. Weights aren't reflected on here, on the Certificate of Analysis. It's not an analytical test. It's performed on the finished product.
Q. So he most likely, he would've called you and said this is out of spec and weights?
A. Call or e-mail, probably e-mail.
Q. The -- excuse me one second.

A. Sure.
Q. The -- I'm looking at M-10. We went over this.
A. This page?
Q. Yes. Yes. And in the bottom block it says on this particular one it says the batch record reviewed; who would have reviewed it?
A. I did.
Q. I thought you didn't get batch records?
A. Well, we refer to this as a batch record, the documentation that we receive we call a batch record whether it's one page or 1000 pages, it's a batch record.
Q. Okay.
So really you looked at the COC and COA?
A. Yes.
Q. Okay.
And then they don't do any inspection there, right, at the distribution center?
A. They do a physical external inspection of the bottles themselves.
Q. To see that they're not broken or --

A. The labeling, verify the labeling.
Q. But they don't test the product in any way?
A. No.
Q. The phone call or the e-mail that you'd get to say that these are out of specification, is there any other documents for that that would reflect what out of spec would be?
A. Typically, like I said earlier, an investigation, we would receive an investigation report. For me to do this, to put a sticky on it, I would have -- it was a heads up to me from Actavis, you know, they were in the midst of writing an investigation report but just letting me know, hey, we've got an issue, just hang on to the product until we resolve it.
Q. What would be -- when you're talking about the weight, would it be the weight of the tablet or the weight of an entire shipment?
A. The weight of a tablet.
MR. FRANKOVITCH: I don't think that I have anything else.
MR. MILLER: Just a couple of quick ones.

* * *

E X A M I N A T I O N

BY MR. MILLER:

Q. When you were asked about the warning letter just now, one of your responses was those that needed to be aware were aware. Concerning the issue of the contents of the warning letter, who is it at Mylan that you believe were those that needed to be aware?

A. Well, it should be our vice president and president of quality.

Q. And who was the vice president?

A. At that time it was Trish Latzo.

Q. And vice president of quality was Chuck Koon?

A. No.

Q. It was who?

A. Not vice president. I don't know if we had a vice president at that time. Trish is highest, Mike would have been the next layer down, whatever his title at that time was, Mike Adams.

Q. So when you say those that needed to be aware were aware, would that include Mike Adams or are you saying it's just Patricia Latzo?

A. All the way down to Chuck.
Q. You didn't know for a fact that they were aware of the warning issues; you are assuming they were aware --
A. Yes.
Q. -- of the issues?
MR. MILLER: That's all I have. I appreciate your time.
MS. MCDONOUGH: We might take five minutes break and just go through our notes, if you can hang in there. We'll be right back.
VIDEOGRAPHER: The time is 3:52; we're going off the record.
* * *
(Brief pause)
* * *
VIDEOGRAPHER: The time is 3:59; we're back on the record.
MR. TABER: Ms. Wolfe, on behalf of Actavis, I have just a couple quick questions for you if you don't mind.
* * *
E X A M I N A T I O N
BY MR. TABER:
Q. With regard to the quality agreement

that you spoke about a few hours ago, was this something that Mylan was doing with all of your outsourced companies, not just Actavis?

A. Yes, that's correct.

Q. And was this done in response to a problem with Actavis or done as a routine part of something that was going on with all of your outsources?

A. It was routine. It was an initiative we started to put contracts in place with all of our outsourced suppliers.

Q. Okay.

MR. TABER: That's all I have. Thank you.

MS. MCDONOUGH: I have no questions.

MR. MILLER: Just a couple follow-up on those thoughts.

* * *

E X A M I N A T I O N

BY MR. MILLER:

Q. Of the other outsource suppliers that you were generating or receiving quality agreements from, did you ever have any of those outsource suppliers have a recall while you were

in the position of QA for third-party production facilities?

A. I'm sorry I hesitated because I'm thinking there was one, but I'm not sure of the timeframe when that happened. So, no, I don't believe so.

MR. MILLER: That's all I have.

MS. MCDONOUGH: Thank you.

VIDEOGRAPHER: The time is 4:00 p.m.; we're going off the record. This concludes the deposition.

MS. MCDONOUGH: She just wants me to say on the record that the client will read and sign the deposition transcript. Thanks.

* * *

(Whereupon, this deposition was concluded at 4:00 p.m.)

* * *

(Whereupon, signature was not waived by the witness.)

* * *

THE STATE OF :
WEST VIRGINIA :
: SS: C E R T I F I C A T E
COUNTY OF OHIO :

I, DEBRA A. VOLK, Court Reporter and Notary Public within and for the State of West Virginia duly commissioned and qualified, do hereby certify that the within-named witness, SUZANNA WOLFE, was by me first duly sworn to testify to the truth, the whole truth and nothing but the truth in the cause aforesaid; and the testimony then given by the witness was by me reduced to stenotype in the presence of the witness; afterwards reduced to Computer Aided Transcription under my direction and control; that the foregoing is a true and correct transcription of the testimony given by said witness.

I do further certify that this testimony was taken at the time and place in the foregoing caption specified, and was completed without adjournment.

I do further certify that I am not a relative, counsel or attorney of either party, or otherwise interested in the event of this action.

IN WITNESS THEREOF, I have hereunto set my hand and affixed my seal of office at Wheeling, West Virginia, on the _____ day of _____, 2010.

_____
DEBRA A. VOLK
Notary Public within and for the State of West Virginia

My Commission Expires:
July 25, 2015

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: DIGITEK PRODUCTS LIABILITY LITIGATION	MDL NO. 1968
THIS DOCUMENT RELATES TO ALL CASES	

* * *

D E P O N E N T' S C E R T I F I C A T E

I, SUZANNA WOLFE, deponent herein, do hereby certify that the above and foregoing transcript is a full, true and complete copy of the proceedings which took place on the 21st day of January, 2010, at the law offices of Jackson Kelly, PLLC, 150 Clay Street, Suite 500, Morgantown, West Virginia 26501.

_____ There are no changes.

_____ Please indicate the within changes.

In certification and verification thereof, I hereunto place my signature on the____ day of_____, 2010.

_____
Deponent

STATE OF_____:
COUNTY OF_____:

Subscribed and sworn to before me a Notary Public on this the _____ day of _____, 2010.

_____
NOTARY PUBLIC

State of _____
County of_____

My Commission Expires: _____

(DAV)

C H A N G E S

I DESIRE TO MAKE THE FOLLOWING CHANGE(S) TO MY DEPOSITION:

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

_____
Deponent

CHANGES (Cont.)

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

_____
Deponent

CHANGES (Cont.)

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE _____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE _____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

_____
Deponent

CHANGES (Cont.)

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE _____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE_____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

PAGE _____ LINE _____
Change desired:_____
_____
Reason for change:_____
_____

_____
Deponent